For years, health care organizations have focused extensively on performance improvement. For example, guest relations strategies have typically focused on helping staff improve their behavior toward their internal and external customers. Productivity strategies have focused on helping people get more work done faster. Although performance improvement is certainly important, without a powerful and complementary strategy to improve the processes themselves, there exists the risk of helping people do the “wrong things” better and faster. All work at all levels needs to be seen as a process.

What is a Process?

A process is a sequence of interrelated activities that converts inputs from suppliers into outputs for customers. Every process has suppliers, inputs, outputs and customers. Inputs can include people, material, equipment, methods and measurements.

Health care delivery processes are different from manufacturing delivery processes in many ways. One important difference is that the ultimate customer, the patient, receives the “product” as it is being produced with little or no opportunity to inspect it prior to delivery. For this reason, the product must be carefully planned to meet customer expectations and professional standards before delivery. Process Management involves the design of processes to develop and deliver products and services that meet the needs of customers with daily controls to prove performance as required, and their continual improvement.

Specifications for a Process Management Model:

1) **Customer expectations and professional standards as a driving force.** Quality management starts with an identification of reasonable, valid customer expectations and professional standards. In order to meet customer expectations and professional standards routinely and focus improvement efforts on high-priority opportunities and problems, your process needs to take its cues from customers whose satisfaction is key to the effectiveness of the particular department and from professionals whose expertise might be needed to define standards on the customer’s behalf.
2) **Operations planned to meet customer expectations integrated with professional standards.** Your process needs to translate your customer’s expectations and your professional standards into operational requirements.

Individuals or groups, known as process owners, are accountable for process performance and have the authority to manage and improve their process. Process owners may range from high-level executives who manage cross-functional processes to staff who run analyzers in the department. Assigning process owners ensures that someone is responsible to manage the process and optimize its effectiveness.

Well written documents that are understood and used by laboratory staff are key to communicating process requirements and ensuring consistency in performance.

Validation consists of a plan for personnel to challenge and document the results, to ensure that the processes work. Whenever a change is necessary, the new process should be validated to ensure that the results will continue to meet the laboratory’s needs and expectations, as well as those of its customers.

Validating a process ensures that the output is what it is intended to be. Validation also provides objective evidence that process variables were considered and control systems evaluated before the process is used in the live environment.

ISO 9000 defines validation as “confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled”.

Validation demonstrates
- that the finished process and product quality is inherent in the process, and
- that each step of the process is designed and controlled to maximize the chances that the process and product will meet established specifications.

ISO 9000 defines verification as “confirmation, through the provision of objective evidence, that specified requirements have been fulfilled”. Verification concerns the process of examining the results of a given activity to determine conformity with the stated requirements for that activity.

Test method performance verification ensures that the test method – as designed by the manufacturer – gives expected results for known samples tested with the equipment and the procedure(s) in place in that particular laboratory.

The laboratory needs to follow all required activities to fulfill governmental and accreditation requirements for method performance specifications. This may include determination of:
- within- and between-run reproducibility
- systematic bias against reference materials of known values
- patient sample comparisons against an existing or a reference method
- limit of detection
- linearity
- reportable ranges and reference intervals (normal values)
- interfering substances, and
- potential sources of error or limiting factors (e.g. sample preparation, calibrators, reference materials, methods, equipment, environmental conditions, sample condition and changes in the operator).
3) **Process Control.** Your process needs to include measures of both process and outcome. You need to develop indicators to determine how well you are meeting customer expectations and professional standards and share this information with your staff.

Once the process is put into place, each operation must be monitored to ensure that it is functioning as designed and that it contributes to achieving the goals and objectives laid out. Tools available for monitoring laboratory processes include:
- A quality assessment (QC) program that reflects the internal needs of the laboratory and meets minimum regulatory requirements
- External assessment (proficiency testing) programs that offer an external peer-based assessment of process output
- Occurrence logs which itemize and characterize problems with process or product output
- Statistical techniques which help personnel to understand process performance and analyze trends
- Quality indicators with thresholds that cause staff to review the process.

4) **Quality Indicators:** You need to translate performance data into meaningful information that can be used to identify priorities for improvement. For example, if you survey customers to monitor their satisfaction, you can show trends in satisfaction and focus improvement efforts on slippage or performance below targeted levels.

You will find that quality indicators are most helpful when they are used to assess vulnerable processes or outcomes. You can target pre-analytical, analytical and post-analytical phases of testing:

- **Pre-Analytical:**
  - Appropriate test choice
  - Patient preparation
  - Patient identification
  - Sample collection
  - Preservative use
  - Sample transport
  - Sample processing
  - Sample distribution
  - Preparation of work lists
  - Record maintenance

- **Analytical:**
  - Methodology
  - Calibration
  - Precision
  - Specimen handling
  - Monitoring equipment and reagents
  - Interfering substances
  - Operator compliance with standard operating procedures (S.O.P.)

- **Post-Analytical:**
  - Correct transcription
It has been stated by Quality Experts Deming and Juran that the overwhelming majority of quality problems are associated with processes; few are caused by the workers themselves.

We all share the responsibility to design and improve the processes within our work environment.