



**INTRODUCING THE**  
**PROsys**  
**QUALITY GATES METHODOLOGY**

*A Requirements-based Technique for Managing Quality*

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## I. PUTTING 'QUALITY' INTO CONTEXT

### *Introduction*

One of the major challenges facing all global companies today is how to get through often complex changes while bringing enhanced quality products and services to their markets and customers more efficiently, yet by using fewer financial, material and human resources. Against the background of a quickly evolving environment and increased competition in the marketplace, many companies are examining the way they work and how they conduct their various operations and management activities.

Over the past few years, PROsys LLC has put considerable effort into developing a framework and tools for achieving effective change and improved quality through better strategic reflection, process redesign and the integration of technological solutions while, at the same time, demonstrating more clearly the interrelationships between the three.

To improve the 'quality' dimension of operations and management calls for:

- the development of a clearly defined Quality Management System,
- the integration of continuous improvement methods into a company's activities, and
- structuring the broader 'Quality Interface' between executive and operations organizations.

This will include consideration of how operations and functional processes contribute to achieving the upper level objectives set by the business, and a review of the business management processes which involve the leaders of the corporation.

### *Focusing on Quality*

A stronger focus on Quality will improve cross-organizational consistency, reliability and efficiency while maximizing the value of the different contributions made through line as well as staff activities.

A well-directed focus on Quality will lead to:

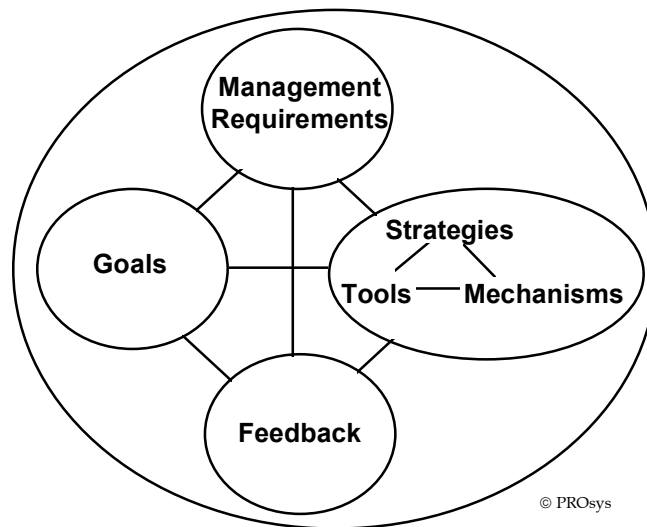
- making investments where value to the business can be demonstrated,
- improving the way the business functions, especially in areas of interdependencies and interactions with other organizational units,
- getting better mileage out of limited resources; doing more, better and faster without automatically increasing costs.
- heightening awareness of opportunities and the potential for improvement in activities, outputs and behavior

## II. MANAGING QUALITY

Quality is defined as *conformance to requirements*. This refers to the capacity of a service, product or output to satisfy fully the requirements of the “customer”, whether internal or external.

Quality Control is the activity of *measuring* conformance to requirements. Feedback is then provided to management on the level of quality of such diverse elements as products or outputs, processes or performance levels, and resources or capabilities.

Quality Management, then, is basically the organization’s reaction to the metrics collected through quality control. This means mechanisms are set up to *make decisions about corrective action* related to the quality of products, processes and resources. The decisions are driven by the measurements taken of conformance to requirements.



A Quality Management System is a *means* to achieve Quality Management. It is made up of six fundamental components:

- *Management Requirements:* Obligations or expectations set by management.
- *Performance Goals:* Related to such specific performance elements as Time, Cost, Quality of Services and Products, Effort and Results.
- *Strategies:* Agreed ways to achieve the Performance Goals while respecting the Management Requirements.
- *Tools:* Methods, approaches and techniques applied within the Strategy (e.g. Quality Gates).
- *Mechanisms:* How the Tools are integrated into operations (e.g. the way decisions are made at the Quality Gates).
- *Feedback:* Performance Metrics which indicate the level of conformance to requirements and the success of chosen Strategies.

### III. QUALITY GATES: AN OVERVIEW

#### *Origins*

A powerful management tool, the ‘Quality Gates’ Method was developed and christened by PROsys, LLC. It has already been successfully applied in a number of different industries, companies and cultures to:

- Improve the performance of projects and processes by managing their Inputs and Outputs.
- Assure that Outputs meet pre-defined management, business and customer Requirements. (Products and Services of a specified Quality level)
- Reduce Cost, Cycle Time and Effort normally consumed by the process. (Often, in reworking Non-Quality Products or fixing unsatisfactory Outputs)

The technique has proven particularly useful for managing the outputs of such intuitive and complex processes as research and development in the IT, automotive and pharmaceutical industries.

#### *A Vision*

The Quality Gates Vision is the Requirement-based Planning, Monitoring and Management of activities and processes.

As Quality is a key driver of most competitive businesses, the vision aims primarily to manage quality through establishing Requirements. This will mean:

- requiring changes to the level of quality of the ‘products’ which come out of the business, and
- using the ‘Quality Gates’ as a mechanism for managing this quality more closely.

Under this Quality Gates Vision, corporate or divisional Requirements become the *Minimum* Requirements for all the business which are generated within the business, whether they are locally, regionally, or centrally managed.

The business’ different operating groups must then have:

- (Local) Business Processes that deliver the ‘Products’ which meet the minimum set of Divisional Requirements.
- Built-in decision points for controlling, adjusting or changing the quality of any ‘Products’ identified in the corporate or divisional Requirements.

#### *Two Types of Quality Gate*

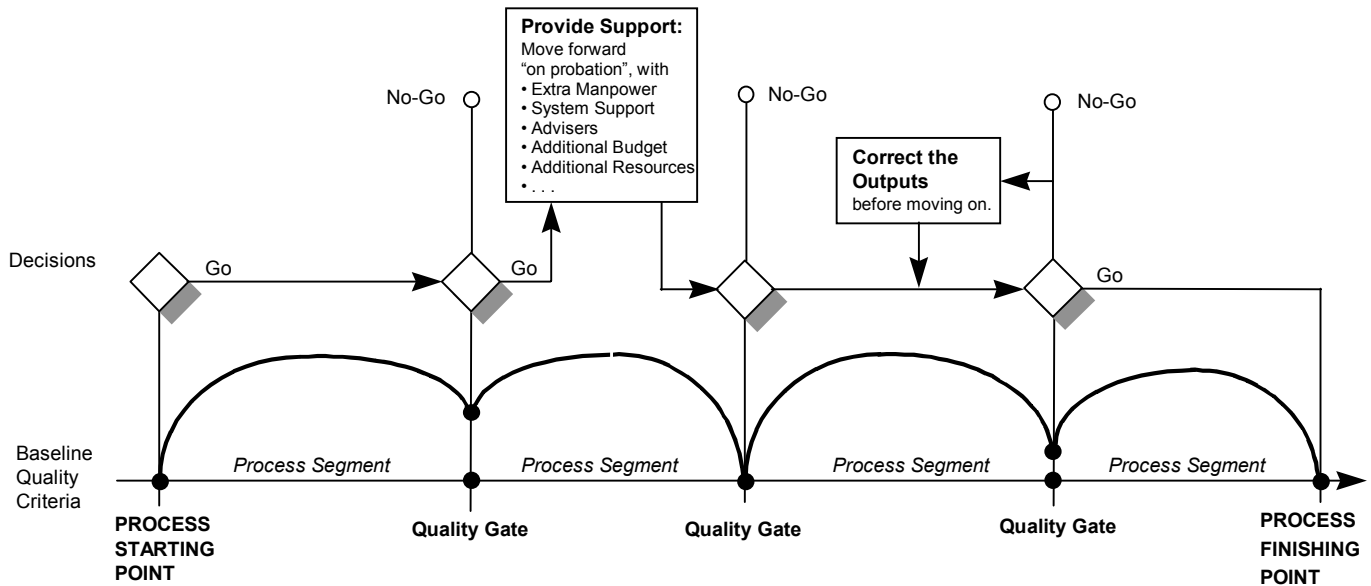
Whether in a Management or Operating Process, a Quality Gate is a control or decision point where a number of Outputs of the process are checked against a pre-defined set of Requirements. The process is not meant to continue down its normal path if the predefined Requirements are not met.

- At the operating level, **Quality Control Gates** are established for monitoring the quality of performance and outputs within operations processes.
- At the management level, **Quality Management Gates** are created for making decisions which will impact the outcomes of a strategy, project or program.

## Quality Gate Components

The components of a Quality Gate are:

- **Location:** “Where does it sit?”  
Where in the business process - whether a management or operating process - the Gate is established.
- **Content:** “What does it look like?”  
A set of predefined criteria against which a quality measurement will be conducted at this point of the process. The ‘content’ element of Quality Gates includes three dimensions:
  - **People:** Requirements related to the skill levels, experience and commitment of those performing the activities within the process. (*Resource requirements*)
  - **Criteria:** The quantitative and qualitative specifications of the products or services expected at this point in the program, project or process. These describe what quality checks the products or services have to pass. (*Output requirements*)
  - **Metrics:** The performance measurements related to the process or to its progress up to the gate. (*Performance Metrics*)
- **Process:** “How does it happen?”  
A definition of how the control and decisions are made, and what happens if the measurement shows that outputs or products do not meet the predefined criteria (*Requirements*). Different levels of management will have different decision-making rules.



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## How They Work

Quality Gates can be likened to the slalom poles in a downhill ski race. The objective of the race is not simply for the skier to get down the hill. He has to pass between all the slalom poles along the way. If the poles weren't there, there would be an infinite number of ways (processes) to get down the hill (*Figure 1*), but time, speed and performance would also vary dramatically.

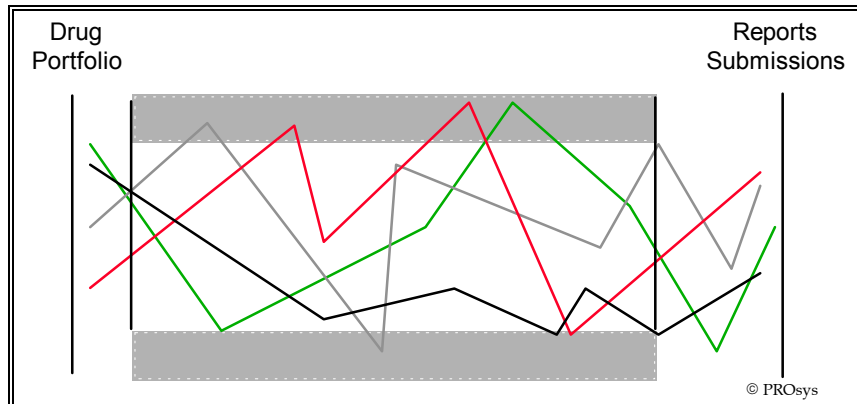


Figure 1

With Quality Gates, the slalom poles still allow variations for each skier, but the level of variation is much more restricted (*Figure 2*).

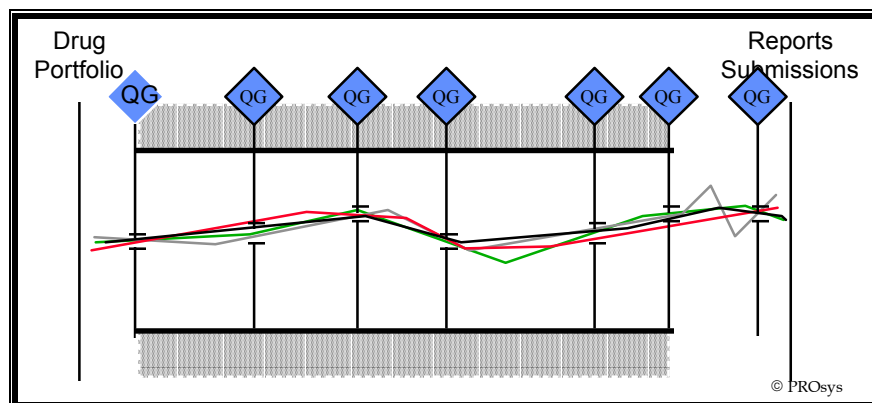


Figure 2

Depending on how the skier arrives at a given pole (Quality Gate), a prediction can be made of his ability to pass successfully to the *next* gate. The criteria measured at the gate are essentially the skier's speed and direction upon arrival at the gate. These tell us how well his process of skiing to the gate has performed. Unless his speed and direction are within a certain range, only drastic corrections in his skiing process will enable him to make the next gate within the pre-defined limits and, hence, finish the race.

In this manner, a set of criteria (in this case, acceptable speed and direction) can be established for every point in the process. If the skier passes a slalom pole (Quality Gate) within the range of acceptable speed and direction, he can continue down the course. If not, he may have to take some special action (such as slowing down temporarily) so that he can make a critical turn to get back on track.

In business terms, this means the outputs of any activity, process, project or program depend on the inputs available, and on the way the work is carried out (the Business Processes). But to ensure the quality of the process itself, we have to both assure the

quality of the inputs to the process (via Entry Criteria) and define Exit Criteria for the activities carried out and for the outputs they produce.

## **IV. GETTING RESULTS**

Quality Gates are based on a results-driven philosophy. Key ingredients are described below.

### ***Quality Management Gates***

At the Management Level (Departmental and Senior), targets (such as acceptable resource levels), timeframes and deadlines are fixed for the *Project or Initiative*. A Quality Management Gate is positioned at each major deadline or target. Specific products or results are generated *within* each defined timeframe. Requirements are defined for these specified Outputs. Outputs and performance are monitored and decisions made to assure alignment between performance and expectations.

### ***Quality Control Gates***

At the Operations level, the Business Process is broken into activity areas. A Quality Control Gate is positioned at the end of specific activities or steps. Specific products are generated through the activity or step. Requirements are defined for the specific products. The products are monitored, and anomalies are reported or corrected within operations.

In *both* cases, the pre-defined requirements represent the minimum acceptable level of quality for the specified output.

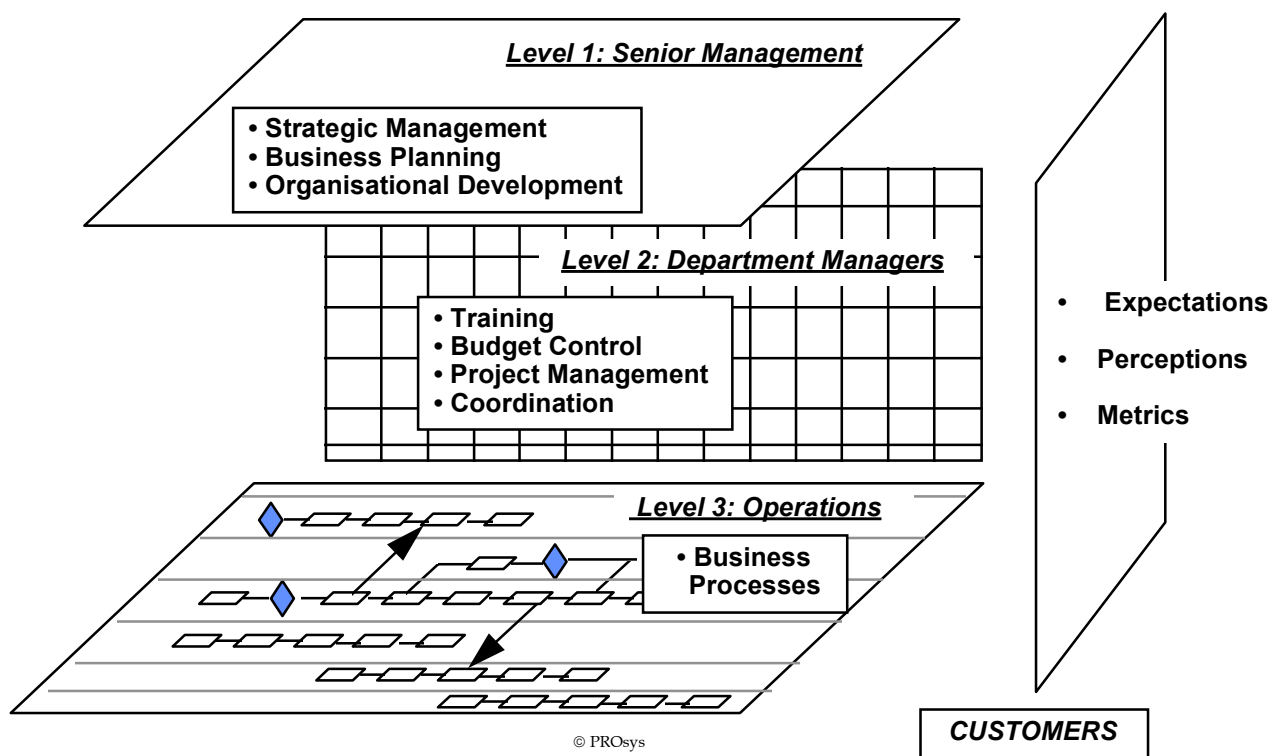
Requirements can also be useful in defining “stretch” goals. Setting requirements against deadlines reinforces the link with strategic objectives and helps employees understand short and long-term expectations.



## *Decision-Making at the Quality Gates*

At Quality Gates where outputs, processes or people deviate from the predefined baseline criteria, there is a need for two types of decision, at three levels of the organization:

- **Content Decisions**
  - To control the quality of the outputs.
  - To control the quality of the activities related to development or production of the outputs.
- **Management Decisions**
  - Related to the five classic roles of the manager: planning, organizing, staffing, controlling and directing the delivery of results.
  - For assuring that the available skills, know-how, tools and resources are capable of delivering to the required level of quality.



As with the slalom example, the Quality Gates Method allows the requirements of the final outputs of complex projects or activities to be back-chained to earlier points in the process. This enables reliable statements to be made about the acceptability of resources, processes, and outputs in the early stages of the project or program. If the criteria are not met at a given decision points, the likelihood of successful completion is reduced and decisions for corrective action have to be made.

## ***The Quality Gates Process***

In generic terms, the Quality Gates Process can be depicted as follows:

The impact assessment of the results on the originally planned downstream process is essentially a risk assessment as to the consequences of requirements that are not met. This is the preparation of making a conscious decision about the downstream process that may take the following directions:

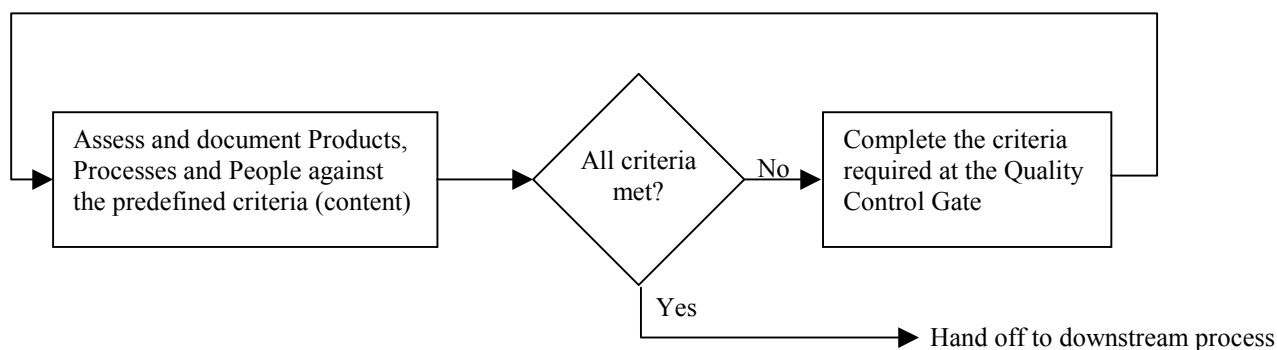
- If all requirements are met, the process downstream process should continue according to plan
- If not all requirements are met, the assessment may come to the conclusion to
  - Stop the process until all or some more requirements are met
  - Build some “extra” activities into the downstream process (with extra resources and maybe a delay) to catch-up for the missed requirements.
  - Build actions into the process to ensure criteria will be met in the future.

An example could be that a monitoring visit turns out insufficient ICF documentation. The trial conduct will most likely not be terminated but the Investigator will be asked to plan sufficient time into the next subject visits to complete the ICF documentation according to the requirements.

## ***The Quality Control Gates Process***

At Quality Control Gates, the primary focus is on the assessment and documentation of the products generated so far, the process as performed to date, and the skills and capabilities required to conduct the process. Though decisions about the downstream process may be made based on the assessment, they will most likely not have any cross-functional implication and usually only prompt the person making the assessment to correct any omissions.

A typical example could be the completion of a protocol approval package prior to submitting the protocol for approval. Should the assessment of all documents included show that the package is not complete, the impact will be the simple adding of a document or form to the package prior to submission. The process hence looks as follows.



**Generic Quality Control Gates Process**

Since Quality Control Gates are implemented on the operational level, the impact assessment is implicit in the criteria and should all be met.

Aside from making the question for quality explicit, the additional purpose of the Quality Control Gate is to:

- Make an explicit statement about the quality of products handed off.
- Document quality for downstream Quality Assurance and Management Processes.

Preferably the documentation should be done in some standard format or system and ideally, the quality documentation should be logically through nomenclature or physically linked to the product itself.

## ***The Quality Management Gates Process***

The Quality Management Gates has three primary purposes:

- To ensure Quality Control was sufficiently performed and documented (Quality Assurance).
- To assess the impact of the actual quality level on downstream processes.
- To identify and define improvements to the process leading up to the Quality Management Gate.

If quality has been documented along the way, Quality Assurance is reduced to ensuring that the quality control documentation is complete and available, combined with statistical checks of the quality control documentation against actual products.

To assess the impact of the actual quality level on the downstream process is a risk assessment process that results in a determination of whether and how the process will continue.

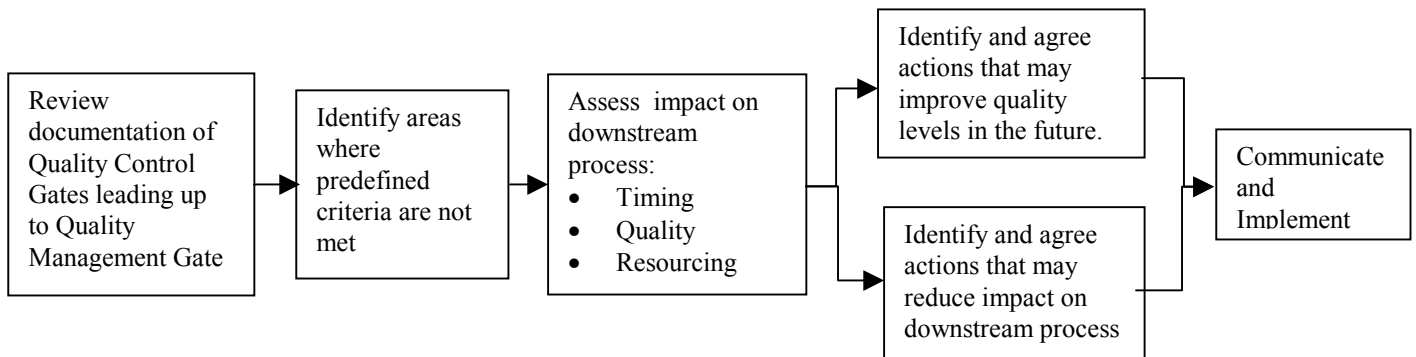
For example, at the time of Analysis and Reporting, a high number of unresolved (not irresolvable) Data Clarifications may lead to rework in table and report production. Whether or not to wait with report development until the number of unresolved Data Clarifications has been reduced to a defined acceptable level is a judgment call that may have significant timeline and resource implications.

The risk assessment and decision usually have to be made by a group of specialists and managers that is:

- Well informed about the actual quality levels (by means of quality control documentation)
- Knowledgeable of the downstream processes and its needs (resources)
- Knowledgeable of the constraints of the organizational units affected (timing of other projects, resource availability)
- Capable of making and implementing decisions

Depending on where in the process, the Quality Management Gate is located and what the downstream process entails, the appropriate management level may be on a supervisory, directors or even executive level (R2-D2 Gate).

Quality Management Gate Process can be depicted as follows.



**Generic Quality Management Gate Process**

## V. MONITORING AND MEASURING RESULTS

Quantifying expectations and measuring results are at the heart of Change Management. This implies fixing long-term objectives, setting short-range targets and collecting information about 'how well we are doing' in relation to them.

Consequently, a procedure for measuring the starting point and the results will provide proof of the effectiveness of the solution or change being implemented. Whether these concern the problem itself, its consequences, management, operations, products or services, there can be no progress unless results are measured, monitored and reported in such a way that corrective action can occur.

We should also remember that measurement is a familiar activity; we are surrounded by measurements - and ways to report them - all the time. For example, we speak of hours and minutes, dates, and miles per hour. To report them, we have clocks, calendars, diaries and speedometers.

### *Measuring the Cost of Quality*

In measuring Quality levels and results, it may be most appropriate to evaluate the 'Price of Nonconformance' as well as the 'Price of Conformance'.

The 'Price of Nonconformance' includes all the expenses incurred by having done things in such a way that they do not respect Requirements. This can include such things as:

- The cost of getting things corrected or doing them over again. Rework consumes human as well as material and financial resources.
- The cost of delay. Waiting for things to get done after their defined deadline or beyond their defined cycle time stimulates non-productive activity (filling in the time or chasing things up) and often forces the displacement of resources (calling in extra troops to make up for the delay).
- The cost of Non-Value-Added activity, such as checking the work of others.

To ascertain the 'Price of Nonconformance': Take everything that would *not* have to be done if everything were done right the first time around. Then, add up the Time and Cost of these misused resources and materials. Research has shown that production companies spend 20% of their sales revenue doing things wrongly and re-doing them. Service companies spend some 35% of their operating costs doing things wrongly and re-doing them.

The 'Price of Conformance' is what it is necessary to spend to make things come out right. This includes most organizational quality or audit functions, all prevention efforts, and any quality-related education. It also covers such areas as procedural or systems validation, and product qualification. The Price of Conformance usually represents 3% to 5% of sales in a well-run company.

The Cost of Quality can generally be collected and assessed in just a few days. Though the first analysis may only get 70% to 85% of the total, the number is often so alarming that it becomes unnecessary to collect the rest.

## VI. METRICS

In the medical field, we speak of ages, heights, weights and blood pressures. We have instruments and record forms to collect and record these measurements accurately. When a series of measurements is to be used to assess a change or a pattern, we refer to them as “metrics”.

As metrics are simply the recorded or documented measurements taken to identify or confirm status, trends or impacts, they can equally be applied to performance, problems and solutions. A useful metric might be ‘number of patient records entered per day’; another metric is ‘number of operator-hours per query’.

Metrics help to understand where you are, and how far you have travelled along the road to improvement. They provide a consistent frame of reference for measuring the problems you are treating and the changes you expect to see.

Three basic groundrules will help in collecting the appropriate metrics as you move around the Problem-Solving Wheel:

- To understand the problem fully, first collect metrics to know the *current* level of performance or quality.
- Try to measure things the process already generates, especially if you are not collecting the metrics yourself. From the operational point of view, creating additional measurables can mean generating Non-Value-Added activity.
- Be sure to align what you measure with what you are trying to achieve. For example, if you’re trying to improve the *results* of some aspect of the business, don’t simply count *activities*. Counting activities will give you the quantity of actions, but won’t give any indication of the *consequences* (results) of those actions.

### ***Program-level metrics***

Related to strategic, upper level Objectives, the program-level metrics established for Quality Management Gates should allow the monitoring and control of an overall project or program. Metrics collected at this level can reflect:

- Degree of progress and/or success of different initiatives.
- Percentage completion against targets.
- Resource consumption across projects.
- Cost versus progress.
- Level of compliance with divisional policy.

### ***Performance metrics***

Implementing Quality Gates such as those defined for the Clinical Process will have an impact on the activities being carried out during Clinical Trials, as well as on the way those activities are managed. Clinical Project Managers should be seeking to monitor and control both the Clinical Trial process and the quality of the products coming out of the process. Metrics can reflect both, and could include yardsticks and measurements that show:

- Cycle time
- Resource consumption
- Human effort
- Cost
- Percentage of Requirements met
- Performance versus expectations for specific activities or products
- Improvement versus targets for specific activities or products

## VII. THE BENEFITS OF DEVELOPING QUALITY MANAGEMENT GATES

For management, developing Quality Gates is a way to confirm what your intuition tells you about program, project and operational performance. The gates ‘force’ the formalizing of individual and organizational experience while defining quality requirements in a standard fashion across the organization. Not only does this foster organizational learning, but it greatly facilitates the implementation of standards in the organization’s processes and products.

Institutionalising Quality Management Gates results in an objective, scheduled review of project or program activities and outputs, providing focus for quality control action. It also improves problem prevention, thus reducing the need for “firefighting” and ensuring specifically targeted intervention when and where it is needed. Allowing for the reduction of external managerial control within operational activities, the Quality Management Gates are used as a pivotal point in program management.

The information generated at Quality Management Gates can also facilitate cross-organizational learning.

## VIII. MANAGEMENT CONSIDERATIONS

A reasonable operating target for would be to align internal company standards. The standard is defined through the Requirements specified at the Quality Gates. However, aiming for this target implies the following for Management, the Organization, Business Processes and Data.

### *Management implications*

#### **Business Requirements**

There will be a need to:

- Define, document and communicate fundamental divisional policies (e.g., all study data will be collected in such a manner that it is reportable).
- Develop a common interpretation of minimum standards for the company and its service providers. This implies a defined, agreed and documented set of minimum requirements

#### **Standardization**

There will be a need to:

- Agree on applying standards and create incentives for compliance; consequences for non-compliance
- Define specific standard Requirements
- Agree on standard management information content
- Agree common terminology
- Implement the standards and terminology

## ***Implications for process redesign***

### **Local Processes**

- In an international business, each country's 'Operational' processes will have to be changed in order to comply with / achieve divisional standards and policies.

### **Divisional Management Processes**

- 'Control' processes will be needed to manage and/or 'police' compliance with Divisional and/or Regional policies and standards.

### **Organisational Learning**

- Processes should be developed for identifying, assessing and transferring 'Best Practices' and organizational learning across countries.

## **IX. IMPLEMENTING THE QUALITY GATES METHOD**

The 'products' listed below will provide a firm foundation for implementing the Quality Gates Method:

- Agreed quality criteria for executive, departmental and operations level products, outputs and activities.
- Policy decisions by management that assure the application of the method.
- Collectable metrics for ascertaining the level of success of the program and of performance within operations.

These products are developed, initiated and confirmed through four Quality Gate Implementation phases.

### **Phase 1: *SET UP THE GATES***

- Define the quality criteria and Quality Management Gates for managing program or project quality.
- Identify and link potential quality improvement needs.
- Carry out a working session with the Management Team to:
  1. Develop understanding: Present and confirm the Quality Gates Method
  2. Gain acceptance:
    - Agree on the approach
    - Confirm targets and deadlines
  3. Anchor commitment:
    - Identify specific Performance or Quality goals / expectations / requirements
    - Agree / validate the Program plan, schedule, roles and responsibilities
    - Assign resources: Select a Steering Committee and assign resources
- Communicate decisions from the Management Team Working Session.
- Prepare training for the Project or Program Team members.

### **Phase 2: *TRAIN THE PROJECT OR PROGRAM TEAM MEMBERS***

- Explain goals, structure and planning.
- Confirm expectations.
- Present and demonstrate tools and methods to be applied.

### **Phase 3: *APPLY THE METHOD***

- Carry out scheduled Quality Management Gate progress / decision meetings to:
  - Validate and evaluate performance and outputs of the program or project.
  - Confirm the respect of defined quality criteria.
  - Identify needed management decisions, and make them.
  - Define corrective action plans and responsibilities.
  - Document solutions.



**Phase 4: *IMPLEMENT THE CORRECTIVE ACTIONS***

- Implement
- Measure Improvements/Progress
- Adjust the solutions or make changes to the process / resources
- Measure Improvements/Progress
- Monitor and report Results

**Ongoing: *REVIEW AND COMMUNICATE***

- Plan and carry out Review Session(s) with managers
- Communicate outcomes and results to employees and management



## **APPENDICES:**

### **1. Definitions**

## ***DEFINITIONS***

A certain level of confusion sometimes accompanies new or different approaches to quality improvement and organizational development. The definitions and explanations which follow are meant to provide a simple framework and to clarify the basic methods we use.

- **QUALITY**

Conformance to Requirements:

The capacity of a service, product or output to satisfy fully the requirements of the “customer”.

- **QUALITY CONTROL**

Activities set up to measure Conformance to Requirements so as to provide feedback to Quality Management on the level of Quality of products or outputs, processes, and resources.

- **QUALITY MANAGEMENT**

Activities set up to make Decisions about corrective actions related to:

- Products
- Processes
- Resources

The decisions are driven by measurements taken of Conformance to Requirements

The generic activities involved in Quality Management are:

- Information Collection
- Performance Evaluation
- Problem Resolution

- **QUALITY MANAGEMENT SYSTEM**

An organized set of interdependent elements for developing and maintaining Quality-related information, analysis, and corrective action. Made up of 6 fundamental components:

- **Management Requirements:** Obligations / expectations set by management.
- **Goals:** Related to specific performance areas and timeframes.
- **Strategies:** A combination of options, decisions, plans and tactics for achieving the performance Goals and respecting the Management Requirements.
- **Tools:** Methods, approaches and techniques applied within the Strategy.
- **Mechanisms:** The way the Tools are integrated into operations.
- **Feedback:** Performance Metrics which indicate the success of chosen Strategies, Tools and Mechanisms.

- **TOOLS**

The methods, approaches and techniques applied to Quality Improvement:

- Documented Requirements
  - Input Requirements
  - Exit Requirements
  - Product / Output Requirements
- Quality Gates
- Quality Metrics
- Training
- Quality Control
- Continuous Improvement
- Root Cause Analysis
- Process Analysis

- **MECHANISMS**

The way the Tools are integrated into operations:

- Quality Review Sessions
- Formal Processes for Problem Treatment:
  - Problem Identification
  - Information Collection
  - Evaluation
  - Resolution
  - Generalization
- The Decision Process at a Quality Gate
- Total Quality Management
- Quality Circles / Quality Improvement Teams
- Continuous Improvement Teams

- **QUALITY GATE**

A decision point in a Business Process where a specified Output is validated against a *pre-defined* set of Requirements. The process will not continue down its normal path if these *pre-defined* Requirements (or “Exit Criteria”) for this point are not met. These Decision Points *drive* Process Quality.

- **TOTAL QUALITY**

Concept based on four Guiding Principles:

- **Meeting the Requirements:** Specifying (Customer) requirements and satisfying them.
- **Error Free Work:** An attitude of work which calls for Zero Defects, or getting it right the first time. The Performance Standard becomes “Zero Error”.
- **Manage by Prevention:** Confront recurring problems. Remedy the causes rather than the symptoms. Anticipate the problems and develop solutions before the error occurs.
- **Cost of Quality:** A measure of the level of non-conformance (“unquality”). Assess the cost of errors, and add this to the cost of detecting errors and the cost of preventing errors in the future.

- **TOTAL QUALITY MANAGEMENT**

The implementation of Quality Management principles at all levels and across all functions of the organization.

Includes:

- Top Management leadership.
- Total involvement of all members of the organisation.
- Rebuilding operational and management practices.
- Deep, systemic, long-term change strategies.

- **COST OF QUALITY**

Ascertained through the measurement of two components:

- **Cost of Non-Conformance:** The cost of everything that would not have to be done if everything were done right in the first place, including wasted materials, rework, man-effort.
- **Cost of Conformance:** The cost of measuring non-conformance and the cost of prevention, including preventive actions, education and training, communication, quality control activities and audits.

- **CONTINUOUS IMPROVEMENT**

An approach to Quality that does not have the short-lived character of a campaign or project. Requires commitment to continuously investing in improvement, step-by-step, year after year.