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Authors: Joseph A. De Feo

6.0. CHAPTER PRELIMINARIES

- High Points of This Chapter
- Compliance and Control Defined
- The Relation to Quality Assurance
- The Elements of the Feedback Loop
- Take Action on the Difference
- The Pyramid of Control
- Planning for Control
- The Control Spreadsheet
- Stages of Control
- Process Conformance
- Product Conformance: Fitness for Purpose
- The Role of Statistical Methods in Control
- The Quality Control System and Policy Manual
- Provision for Audits
- Tasks for Leaders
- References

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6.1. High Points of This Chapter

1. The quality control process is a universal managerial process for conducting operations so as to provide stability—to prevent adverse change and to "maintain the status quo." Quality control takes place by use of the feedback loop.
2. Each feature of the product or process becomes a control subject—a center around which the feedback loop is built. As much as possible, human control should be done by the workforce—the office clerical force, factory workers, salespersons, etc.
3. The flow diagram is widely used during the planning of quality controls. The weakest link in facilities control has been adherence to schedule.
4. To ensure strict adherence to schedule requires an independent audit.
5. Knowing which process variable is dominant helps planners during allocation of resources and priorities.
6. The design for process control should provide the tools needed to help the operating forces distinguish between real change and false alarms. It is most desirable to provide umpires with tools that can help to distinguish between special causes and common causes. An elegant tool for this purpose is the Shewhart control chart (or just control chart). The criteria for self-control are applicable to processes in all functions and all levels, from general manager to nonsupervisory worker.
7. Responsibility for results should be keyed to controllability. Ideally the decision of whether the process conforms to process quality goals should be made by the workforce.
8. To make use of self-inspection requires meeting several essential criteria: Quality is number one; mutual confidence, self-control, training, and certification are the others. Personnel who are assigned to make product conformance decisions should be provided with clear definitions of responsibility as well as guidelines for decision making.
9. The proper sequence in managing is first to establish goals and then to plan how to meet those goals, including the choice of the appropriate tools. The planning for quality control should provide an information network that can serve all decision makers.

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6.2. Compliance and Control Defined

Compliance or quality control is the third universal process in the Juran Trilogy. The others are quality planning in and quality improvement. The Juran Trilogy diagram (Fig. 6.1) shows the interrelation of these processes.

Figure 6.1 *Juran Trilogy diagram. (Juran Institute, Inc., 1986.)*

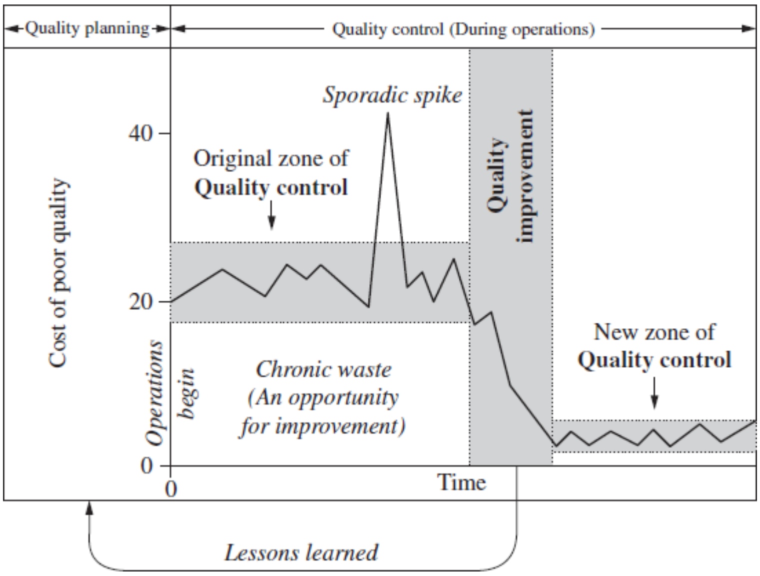


Figure 6.1 is used in several other chapters in this handbook to describe the relationships between planning, improvement, and control—the fundamental managerial processes in quality management. What is important for this chapter is to concentrate on the two "zones of control."

In Fig. 6.1, we can easily see that although the process is in control in the middle of the chart, we are running the process at an unacceptable level of performance and "waste." What is necessary here is not more control, but improvement—actions to change the level of performance.

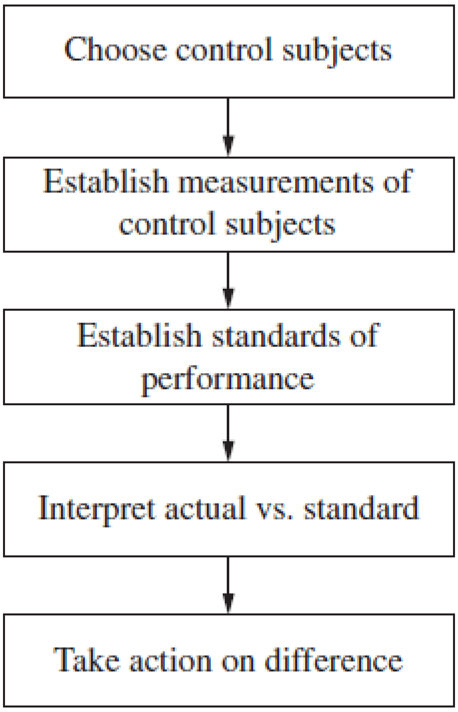
After the improvements have been made, a new level of performance has been achieved. Now it is important to establish new controls at this level to prevent the performance level from deteriorating to the previous level or even worse. This is indicated by the second zone of control.

The term "control of quality" emerged early in the twentieth century (Radford 1917, 1922). The concept was to broaden the approach to achieving quality, from the then-prevailing after-the-fact inspection (detection control) to what we now call "prevention (proactive control)." For a few decades, the word "control" had a broad meaning, which included the concept of quality planning. Then came events that narrowed the meaning of "quality control." The "statistical quality control" movement gave the impression that quality control consisted of using statistical methods. The "reliability" movement claimed that quality control applied only to quality at the time of test but not during service life.

In the United States, the term "quality control" now often has the meaning defined previously. It is a piece of a "performance excellence, operational excellence, business excellence, or total quality program," which are now used interchangeably to comprise the all-embracing term to describe the methods, tools, and techniques to manage the quality of an organization.

In Japan, the term "quality control" retains a broad meaning. Their "total quality control" is equivalent to our term "business excellence." In 1997, the Union of Japanese Scientists and Engineers (JUSE) adopted the term Total Quality Management (TQM) to replace Total Quality Control (TQC) to more closely align themselves with the more common terminology used in the rest of the world. Figure 6.2 shows the input-output features of this step.

Figure 6.2 *Input-output diagram.*



In Fig. 6.2, the input is operating process features, or key control characteristics, developed to produce the product features, or key product characteristics, required to meet customer needs. The output consists of a system of product and process controls, which can provide stability to the operating process.

A key product characteristic is a product characteristic for which reasonably anticipated variation *could significantly affect* a product's safety, compliance to government regulations, performance, or fit.

Key product characteristics (KPCs) are *outputs from a process that are measurable* on, within, or about the product itself. They are the outputs perceived by the customer. Examples of KPCs include

- KPCs "On:" the product: width, thickness, coating adherence, surface cleanliness, etc.
- KPCs "Within:" the product: hardness, density, tensile strength, mass, etc.
- KPCs "About:" the product: performance, weight, etc.

In general, key control characteristics (KCCs) are *inputs that affect the outputs* (KPCs). They are unseen by the customer and are measurable only when they occur. A KCC is

- A process parameter for which variation must be controlled around some target value to ensure that variation in a KPC is maintained around its target values during manufacturing and assembly.
- A process parameter for which reduction in variation will reduce the variation of a KPC.
- Directly traceable to a KPC.
- Particularly significant in ensuring a KPC achieves target value.
- Not specified on a product drawing or product documentation.

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6.3. The Relation to Quality Assurance

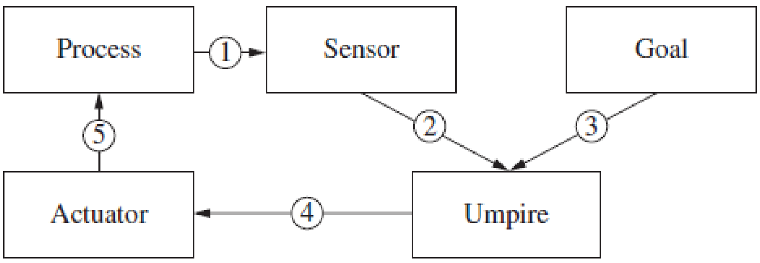
Quality control and quality assurance have much in common. Each evaluates performance. Each compares performance to goals. Each acts on the difference. However, they also differ from each other. Quality control has as its primary purpose maintaining control. Performance is evaluated during operations, and performance is compared to targets during operations. In the process, metrics are utilized to monitor adherence to standards. The resulting information is received and used by the employees.

The main purpose of quality assurance is to verify that control is being maintained. Performance is evaluated after operations, and the resulting information is provided to both the employees and others who have a need to know. Results metrics are utilized to determine conformance to customer needs and expectations. Others may include leadership, plant, functional; corporate staffs; regulatory bodies; customers; and the general public.

6.3.1. The Feedback Loop

Quality control takes place by use of the feedback loop. A generic form of the feedback loop is shown in **Fig. 6.3**.

Figure 6.3 *Feedback loop.*



The progression of steps in **Fig. 6.3** is as follows:

1. A sensor is "plugged in" to evaluate the actual quality of the control subject—the product or process feature in question. The performance of a process may be determined directly by evaluation of the process feature, or indirectly by evaluation of the product feature—the product "tells" on the process.
2. The sensor reports the performance to an umpire.
3. The umpire also receives information on the quality goal or standard.
4. The umpire compares actual performance to standard. If the difference is too great, the umpire energizes an actuator.
5. The actuator stimulates the process (whether human or technological) to change the performance so as to bring quality into line with the quality goal.

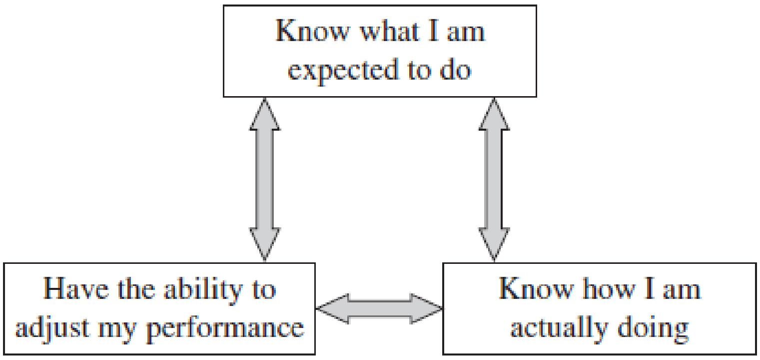
6. The process responds by restoring conformance.

Note that in Fig. 6.3 the elements of the feedback loop are functions. These functions are universal for all applications, but responsibility for carrying out these functions can vary widely. Much control is carried out through automated feedback loops. No human beings are involved. Common examples are the thermostat used to control temperature and the cruise control used in automobiles to control speed.

Another form of control is self-control carried out by employees. An example of such self-control is the village artisan who performs every one of the steps of the feedback loop. The artisan chooses the control subjects based on understanding the needs of customers, sets the quality targets to meet the needs, senses the actual quality performance, judges conformance, and becomes the actuator in the event of nonconformance.

This concept of self-control is illustrated in Fig. 6.4. The essential elements here are the need for the employee or work team to know what they are expected to do, to know how they are actually doing, and to have the means to regulate performance. This implies that they have a capable process and have the tools, skills, and knowledge necessary to make the adjustments and the authority to do so.

Figure 6.4 *Concept of self-control. (The Juran Institute, Inc.)*



A further common form of feedback loop involves office clerks or factory workers whose work is reviewed by umpires in the form of inspectors. This design of a feedback loop is largely the result of the Taylor Management System adopted in the early twentieth century. It focused on the separation of planning for quality from the execution or operations. The Taylor Management System emerged a century ago and contributed greatly to increasing productivity. However, the effect on quality was largely negative. The negative impact resulted in large costs associated with poor quality, products and services that have higher levels of failure, and customer dissatisfaction.

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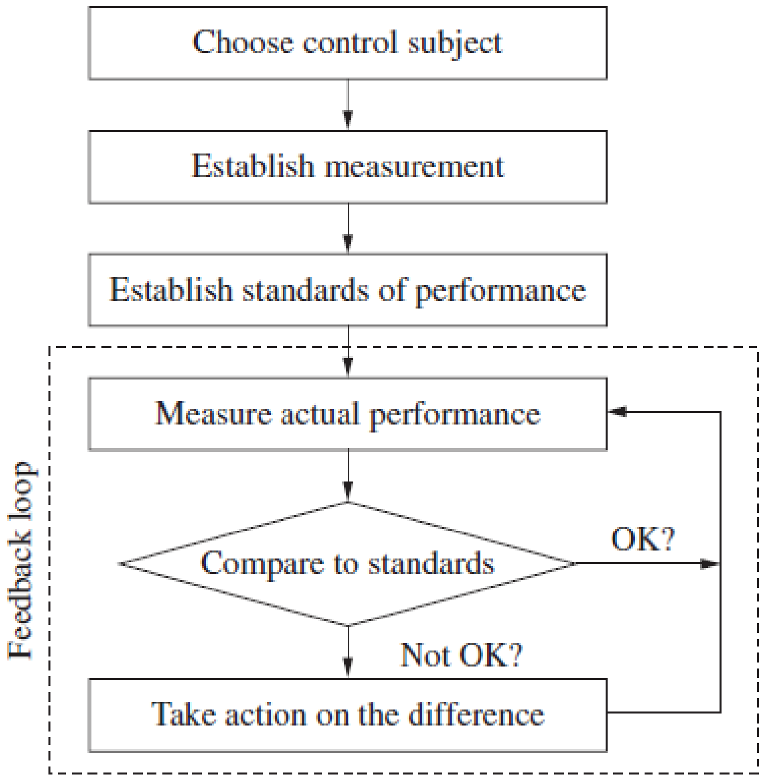
6.4. The Elements of the Feedback Loop

The feedback loop is a universal. It is fundamental to maintaining control of every process. It applies to all types of operations, whether in service industries or manufacturing industries, whether for profit or not. The feedback loop applies to all levels in the hierarchy, from the chief executive officer to the members of the workforce. However, there is wide variation in the nature of the elements of the feedback loop.

In **Fig. 6.5**, a simple flowchart is shown describing the control process with the simple universal feedback loop imbedded.

Figure 6.5 *Simple flowchart describing the control process.*



6.4.1. The Control Subjects

Each feature of the product (goods and services) or process becomes a control subject (the specific attribute or variable to be controlled)—a center around which the feedback loop is built. The critical first step is to choose the control subject. To choose control subjects, you should identify the major work processes and products, define the objectives of the work processes; succinctly define the work processes; identify the customers of the process, and then select the control subjects (KPCs and/or KCCs). Control subjects are derived from multiple sources, which include

- Stated customer needs for product features
- Translated "voice of the customer" needs into product features
- Defined process features that create the product or service features
- Industry and government standards and regulations (i.e., Sarbanes Oxley, ISO 9000, etc.)
- Need to protect human safety and the environment (i.e., OSHA, ISO 14000)
- Need to avoid side effects such as irritations to stakeholders, employees, or to a neighboring community
- Failure mode and effects analyses
- Control plans
- Results of design of experiments

At the staff level, control subjects consist mainly of product and process features defined in technical specifications and procedures manuals. At managerial levels, the control subjects are broader and increasingly business oriented. Emphasis shifts to customer needs and to competition in the marketplace. This shift in emphasis then demands broader control subjects, which, in turn, have an influence on the remaining steps of the feedback loop.

6.4.2. Establish Measurement

After choosing the control subjects, the next step is to establish the means of measuring the actual performance of the process or the quality level of the goods or services being created. Measurement is one of the most difficult tasks of management and is discussed in almost every chapter of this handbook. In establishing the measurement, we need to clearly specify the means of measuring (the sensor), the accuracy and precision of the measurement tool, the unit of measure, the frequency of measuring, the means by which data will be recorded, the format for reporting the data, the analysis to be made on the data to convert it to usable information, and who will make the measurement. In establishing the unit of measure, one should select a unit of measure that is understandable, provides an agreed-upon basis for decision making, is customer focused, and can be applied broadly.

6.4.3. Establish Standards of Performance: Product Goals and Process Goals

For each control subject it is necessary to establish a standard of performance—a target or goal (also metrics, objectives, etc.). A standard of performance is an aimed-at target toward which work is expended. Table 6.1 gives some examples of control subjects and the associated goals.

Table 6.1 *Control Subjects and Associated Quality Goals*

Control Subject	Goal
Vehicle mileage	Minimum of 25 mi/gal highway driving
Overnight delivery	99.5% delivered prior to 10:30 A.M. next morning
Reliability	Fewer than three failures in 25 years of service
Temperature	Minimum 505°F; maximum 515°F
Purchase-order error rate	No more than 3 errors/1000 purchase orders
Competitive performance	Equal or better than top three competitors on six factors
Customer satisfaction	90% or better rate, service outstanding or excellent
Customer retention	95% retention of key customers from year to year
Customer loyalty	100% of market share of over 80% of customers

The prime goal for products and services is to meet customer needs. Industrial customers often specify their needs with some degree of precision. Such specified needs then become goals for the producing company. In contrast, consumers tend to state their needs in vague terms. Such statements must then be translated into the language of the producer in order to become product goals.

Other goals for products that are also important are those for reliability and durability. Whether the products and services meet these goals can have a critical impact on customer satisfaction, loyalty, and overall costs. The failures of products under warranty can seriously affect the profitability of a company through both direct and indirect costs (loss of repeat sales, word of mouth, etc.).

The processes that produce products have two sets of goals:

- To produce products and services that meet customer needs. Ideally, each and every unit produced should meet customer needs (meet specifications)
- To operate in a stable and predictable manner. In the dialect of the quality specialist, each process should be "in a state of control." We will later elaborate on this, in the section "Process Conformance"

Quality targets may also be established for functions, departments, or people. Performance against such goals then becomes an input to the company's scorecard, dashboard, and reward system. Ideally such goals should be

- *Legitimate*. They should have undoubted official status.
- *Measurable*. They can be communicated with precision.
- *Attainable*. As evidenced by the fact that they have already been attained by others.

- *Equitable*. Attainability should be reasonably alike for individuals with comparable responsibilities.

Quality goals may be set from a combination of the following bases:

- Goals for product and service features and process features are largely based on technological analysis
- Goals for functions, departments, and people should be based on the need of the business and external benchmarking rather than historical performance

In recent years, quality goals used at the highest levels of an organization have become commonplace. Establishing long-term goals such as reducing the costs of poor quality or becoming best in class have become a normal part of strategic business plans. The emerging practice is to establish goals on "metrics that matter," such as meeting customers' needs, exceeding the competition, maintaining a high pace of improvement, improving the effectiveness of business processes, and setting stretch goals to avoid failure-prone products and processes.

6.4.4. Measure Actual Performance

A critical step in controlling quality characteristics is to measure the actual performance of a process as precisely as possible. To do this requires measuring with a "sensor." A sensor is a device or a person that makes the actual measurement.

6.4.5. The Sensor

A "sensor" is a specialized detecting device. It is designed to recognize the presence and intensity of certain phenomena and to convert the resulting data into "information." This information then becomes the basis of decision making. At the lower levels of an organization, the information is often on a real-time basis and is used for daily control. At higher levels, the information is summarized in various ways to provide broader measures, detect trends, and identify the vital few problems.

The wide variety of control subjects requires a wide variety of sensors. A major category is the numerous technological instruments used to measure product features and process features. Familiar examples are thermometers, clocks, and weight scales. Another major category of sensors is the data systems and associated reports, which supply summarized information to the managerial hierarchy. Yet another category involves the use of human beings as sensors. Questionnaires, surveys, focus groups, and interviews are also forms of sensors.

Sensing for control is done on an organization level. Information is needed to manage for the short and long term. This has led to the use of computers to aid in the sensing and in converting the resulting data into information.

Most sensors provide their evaluations in terms of a unit of measure—a defined amount of some feature—that permits evaluation of that feature in numbers or pictures. Familiar examples of units of measure are degrees of temperature, hours, inches, and tons. Human beings do a considerable amount of sensing. Such sensing is subject to numerous sources of error. The use of pictures as a standard to comparison can help reduce human errors. Also of vital importance to alleviate human errors is the application of detailed instructions.

6.4.6. Compare to Standards

The act of comparing to standards is often seen as the role of an umpire. The umpire may be a person or a technological device. Either way, the umpire may be called on to carry out any or all of the following activities:

- Compare the actual process performance to the targets
- Interpret the observed difference (if any); determine if there is conformance to the target
- Decide on the action to be take
- Stimulate corrective action
- Record the results

These activities require elaboration and will be examined more closely in an upcoming section.

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6.5. Take Action on the Difference

In any well-functioning control system we need a means of taking action on any difference between desired standards of performance and actual performance. For this we need an actuator. This device (human or technological or both) is the means for stimulating action to restore conformance. At the operations or employee level, it may be a keypad for giving orders to a centralized computer database, a change in a new procedure, a new specification document, or a new setting of a dial to adjust a machine to the right measure. At the management level, it may be a memorandum to subordinates, a new company policy, or a team to change a process.

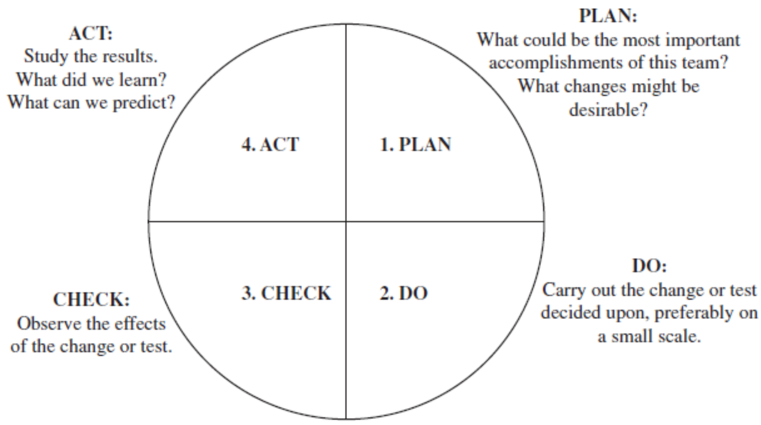
6.5.1. The Key Process

In the preceding discussion we have assumed a process. This may also be human or technological or both. It is the means for producing the product and service features, each of which requires control subjects to ensure conformance to specifications. A process does all work. A process consists of inputs, labor, technology, procedures, energy, materials, and outputs.

6.5.2. Taking Corrective Action

There are many ways of taking corrective action to troubleshoot a process and return to the "status quo." A popular example of a root cause and corrective action method is the so-called PDCA or PDSA Cycle (first popularized by Walter Shewhart and then by Dr. Deming as the Deming Wheel) as shown in **Fig. 6.6**. Deming (1986) referred to this as the Shewhart Cycle, which is the name many still use when describing this version of the feedback loop.

Figure 6.6 *The PDCA Cycle. (Shewhart and Deming, 1986.)*



In this example, the feedback loop is divided into four steps labeled Plan, Do, Check, and Act (PDCA) or Plan, Do, Study, Act (PDSA). This model is used by many health care and service industries. These steps correspond roughly to the following:

- "Plan" includes choosing control subjects and setting goals.
- "Do" includes running and monitoring the process.
- "Check" or "Study" includes sensing and umpiring.
- "Act" includes stimulating the actuator and taking corrective action.

An early version of the PDCA cycle was included in W. Edwards Deming's first lectures in Japan (Deming 1950). Since then, additional versions have been used, like PDSA, PDCA, RCCA, and so on.

Some of these versions have attempted to label the PDCA cycle in ways that make it serve as a universal series of steps for both control and improvement. The authors feel that this confuses matters, since two very different processes are involved. Our experience is that all organizations should define two separate methods. One is to take corrective action on a "sporadic change" in performance.

RCCA, PDSA, and PDCA differ from improvement methods like Six Sigma in that the scope of the problem lends itself to a simpler, less complex analysis to find the root cause of a "sporadic problem." RCCA analytical and communication tools contribute to the reduction of day-to-day problems that plague processes. Tools utilized for analysis and diagnosis of sporadic spikes typically take the form of graphical tools with less emphasis on statistical applications. Often many organizations that have been trained in RCCA and the like do not have the right tools and methods to solve chronic problems. It is best to use the Six Sigma D-M-A-I-C improvement methods.