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Defining the best quality-control systems by design and inspection

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Not all of the many approaches to quality control are equally effective. Nonconformities in laboratory testing are caused basically by excessive process variation and mistakes. Statistical quality control can effectively control process variation, but it cannot detect or prevent most mistakes. Because mistakes or blunders are frequently the dominant source of nonconformities, we conclude that statistical quality control by itself is not effective. I explore the 100% inspection methods essential for controlling mistakes. Unlike the inspection techniques that Deming described as ineffective, the new "source" inspection methods can detect mistakes and enable corrections before nonconformities are generated, achieving the highest degree of quality at a fraction of the cost of traditional methods. Key relationships between task complexity and nonconformity rates are also described, along with cultural changes that are essential for implementing the best quality-control practices.

INDEXING TERMS: mistake-proofing • statistical quality control • task complexity • defects • nonconformities

Recently, biopsy tissue was removed from a friend to determine whether her breast cancer had spread to her lymph nodes. The lymph nodes were lost between the operating room and the laboratory, and she is now enduring painful chemotherapy even though the cancer may not have metastasized. Mistakes like these are the dominant source of nonconformities today in virtually every industry. As this case illustrates, mistakes often lead to lost productivity and pain and suffering for those we strive to serve. Mistakes cannot be controlled by traditional methods like statistical quality control (SQC), pointing to the need for a more rigorous approach to quality control.

To understand the best methods for eliminating nonconformities in any process, one must first understand the sources of nonconformities and the most effective ways to eliminate or control each type. Toward this goal I review the evolution of quality control and modern quality-control methods that are achieving revolutionary reductions in defect rates.

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Traditional Quality Control

A QUALITY SYSTEM

The goal of every operation or production system is to generate a useful product. The product may be a service, information, or physical object. Each production cycle begins with inputs that are transformed by a process into a more desired state or into the product. Shingo *[1]* classified production inputs to every process as: man (person executing or controlling the process); machine (equipment or machinery used in the execution of the process); material (raw materials or parts required in the process); methods (procedures and sequence used to execute the process); and information (work instructions, data, and sensor readings that guide process execution).

In each process, excessive variations and errors can cause nonconformities, with three undesirable consequences: (*a*) scrapped or wasted resources; (*b*) degraded process throughput; (*c*) "contamination" from undetected nonconformities, reducing the value of the product to the customer.

The goal of quality control in every production system is to (*a*) eliminate nonconformities and their consequences, (*b*) eliminate rework and wasted resources, and (*c*) achieve these goals at the lowest possible cost.

EVOLUTION OF QUALITY CONTROL

Most quality-control methods were initially developed to aid manufacturing. This is not surprising because high-volume production typically requires many repetitions involving a controlled sequence of operations. Where operations are frequently repeated, it is easier to recognize processing errors and identify appropriate control measures. Historically, the first quality-control methods were based on judgment inspections.

Judgment inspections. The demand for manufactured goods increased dramatically in the period before 1900, when large variations from part to part were common. Skilled craftsmen performed the final alterations on each part in an assembly to assure that the parts mated and functioned properly. Using a "file to fit" approach, craftsmen would inspect and adjust part features repeatedly until an acceptable match was achieved.

The quality control used by craftsmen was based on judgment inspection; the worker decided whether each part in an assembly was acceptable or unacceptable. If the part was unacceptable, the worker would try to rework the parts or else discard them if they could not be adjusted to function properly. The relationships between judgment inspections, the production process, and associated decisions (Fig. 1) show that the inspection occurs after the product is made. Thus, judgment inspections can detect nonconformities only after they have been generated.

We still use judgment inspections today. For example, a chemist may mix chemicals in a test tube and hold the test tube up to a light to determine whether the chemicals are adequately mixed. According to the appearance of the mixture, the chemist may determine that mixing is adequate or that more stirring or agitation is necessary. If the mixture is of the wrong color, it may be discarded because the improper material quantities have been used.

Gage inspection: a refinement of judgment inspections. Although Eli Whitney developed the concept of interchangeable parts, Henry Ford is credited with its widespread acceptance (Womack et al. *[2]*). Ford recognized that part to part variability was a major impediment to achieving truly interchangeable parts. Ford continued to use judgment inspections to control part features but replaced visual inspection with gaging inspection to achieve greater consistency. As a procedure to overcome differences in gaging from one location to another, gages had to be traceable to standards throughout the Ford production system. This effective implementation increased interest in international measurement standards and played a key role in development of mass production.

SQC inspections. The next major breakthrough in quality control was made by a team led by Shewhart at Bell Laboratories *[3]*. This team demonstrated that variation on the production floor could be described statistically and that statistical data could identify when a process was drifting out of control. Statistical data were useful in guiding adjustment of the process to reduce the probability that nonconforming product would be produced.

The SQC inspection process illustrated in Fig. 2 had many advantages relative to judgment inspections. SQC relies on sampling inspection, which substantially reduces the amount of inspection activity. Unlike judgment inspection, SQC provides a feedback for the production process that helps to reduce the likelihood of nonconformities. This resulted in dramatically lower defect rates on the production floor, often in the range of 2 000 to 20 000 nonconforming parts per million (ppm). The improvement in quality achieved through SQC reduced rework, scrap, and wasted resources.

Deming estimated that 94% of the process variation stemmed from common causes and that 6% could be traced to special causes *[4]*. These impressions were formed in a time frame when tolerancing, gaging, and SQC methods were evolving.

The development of SQC led to a revolutionary reduction in nonconformity rates and hence many advances and developments in the understanding of quality and quality control. Subsequent changes, however, have generally led to incremental reductions in nonconformities. In the mid-1980s, the Department of Defense strongly stressed implementation of total quality management, a quality approach emphasizing operation "in a framework of statistical control" *[5]*. However, >60% of the companies implementing total quality management see <10% reduction in nonconformities *[6]*.

Motorola's Six Sigma. Perhaps the most widely recognized recent development in SQC methods is Motorola's Six Sigma *[7]*. According to traditional SQC, a process is in control if the variation measured in standard deviations (σ or sigma) is less than one-third the difference between the control limits and the process mean; i.e., the tradi-

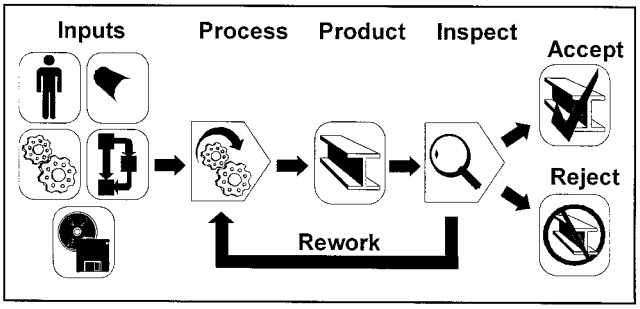

Fig. 1. Judgment inspections are made after a process has transformed inputs into a product.

The inputs to each process may include the man, materials, methods, information, and machines as illustrated clockwise at the left of the figure. Based on inspection, the product is accepted, rejected, or reworked.

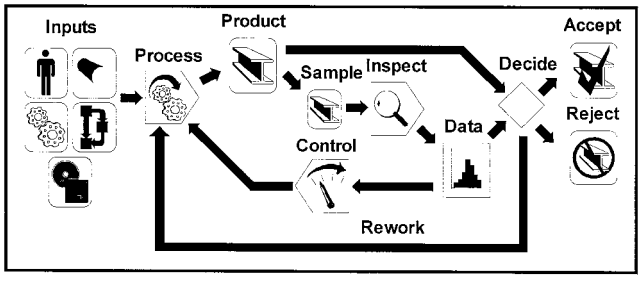

Fig. 2. SQC inspections begin with a sample drawn from products downstream of a process.

Data from the inspected sample is collected and described statistically. Data are used to provide feedback control for the process and to decide whether the product or lot is accepted, rejected, or submitted for rework.

tional distance between the mean and any control limit is at least 3σ. However, Motorola concluded that quality leaders achieved fewer defects by reducing process variations. They estimated that defects would be cut 1000-fold if the process variation could be held to one-sixth the difference between process mean and control limits, or 6σ variation control.

Roughly 6 years after aggressively implementing Six Sigma methods, Motorola's average defect rate was ~1000 ppm *[8]*. Although this represented a substantial improvement in quality control for Motorola, it falls far short of the theoretical results predicted by the Six Sigma theory.

A New Quality-Control Paradigm

In Japan, companies that set the standard for quality are achieving lower defect rates than companies that rely on SQC-based methods. To achieve similar results, we must understand how their approach to quality control differs from traditional methods and why these differences are important.

MISTAKES—A DOMINANT SOURCE OF DEFECTS

If we study a simple process such as mixing specified quantities of two liquids in a beaker, we can describe the quantity of each of the liquids in terms of variation, similar to the traditional statistical approach, but sometimes a person may forget to put one of the liquids into the beaker, may add two measures of the same liquid into the mixture, may inadvertently forget to stir the mixture, or may select an improper chemical for the mixture. In contrast to variation, we define such mistakes or blunders as: (*a*) the execution of a prohibited action; (*b*) the failure to perform a required action; or (*c*) misinterpretation of information essential for the correct execution of a task.

In many cases, mistakes are detected and corrected, often after the mistake has resulted in a nonconforming product. However, about once in 10 000 to once in every 100 000 repetitions, each type of mistake will be undetected and uncorrected *[9]*.

Types of mistakes. Although each type of mistake is exceptionally rare, many types can occur. One book on mistake-proofing for manufacturing listed the following types of mistakes in order of their frequency of occurrence *[1]*: (*a*) omitted processes; (*b*) processing mistakes; (*c*) mistakes setting up workpiece; (*d*) missing parts; (*e*) wrong parts; (*f*) processing the wrong workpiece; (*g*) misoperation; (*h*) adjustment mistake; (*i*) equipment not set up properly; and (*j*) tools and jigs improperly prepared. These mistakes are leading causes of nonconformities. These same mistakes can occur in the clinical laboratory environment, although they may be described in slightly different terms. For example, an omitted label on a specimen is one type of missing part.

As the control of variation has improved, the relative importance of mistakes in the total nonconformity rates has increased. Several researchers have reached this same conclusion over the last 30 or 40 years (see review *[8]*). For example, in the study of 23 000 production defects, Rook *[10]* concluded that 82% originated from mistakes.

We can frequently find evidence that mistakes are dominant quality problems. For example, a 1995 article in the *Journal of the American Medical Association [11]* stated that 6.5% of the patients entering hospitals experience adverse drug effects caused by prescription errors. The seriousness of these errors is highlighted by the fact that ~1% of the adverse drug effects resulted in fatalities.

Mistakes in the clinical laboratory. Mistakes are also a common cause of nonconformities in clinical laboratories. Lapworth and Teal *[12]* cited two studies reporting that clinical laboratory mistake rates were 0.3–2.3%. Although their own study identified an average mistake rate of only 0.05%, their mistake detection methods admittedly could not detect many types of error. Boone *[13]* observed overall mistake rates of ~100 per 100 000 (0.1%) in a hospital clinical laboratory. Similarly, in a study of turnaround times for urgent clinical tests, Pellar et al. *[14]* found that mistakes were a leading source of delays.

We have observed that human inspection methods based on subjective criteria, typical of the type described in these studies, generally fail to detect most of the nonconformities generated by mistakes. Thus, the data on clinical laboratory mistake rates are not inconsistent with an overall nonconformity rate as high as 1% to 2% of all test results generated! Such a nonconformity rate resulting from mistakes would be comparable with those observed in other settings.

The product of a clinical laboratory is the report of a test result that guides patient care. The clinical laboratory studies cited previously identified mistakes that occurred at virtually every stage of the process preceding the delivery of the laboratory report. A few types of mistakes identified in these studies are shown in Table 1. The causes of nonconformities listed in Table 1 differ from the traditional view of variation and demonstrate that mistakes are a strong quality concern in the laboratory.

SQC CANNOT CONTROL MISTAKES

Mistakes often result in outcomes that lie completely outside of the most extreme limits predicted by variation models. For example, a typical distribution of the quantity of a chemical used in a process predicts that the quantity would never be zero, an outcome that could occur if the chemical is accidentally omitted. Our own experience suggests that the process variation, measured by the variance, roughly doubles when the outcome of mistakes are included in large samples. This suggests that special causes, including mistakes, are far more significant than Deming or others anticipated *[4]*.

A key principle is that SQC cannot control mistakes. Because each type of mistake is a rare event, the frequency of mistakes cannot be predicted by sampling methods.

Table 1. Typical mistakes leading to clinical laboratory nonconformities identified during three stages of the process *[12–14]*.

Specimen collection	Laboratory analysis	Reporting
Wrong form	Specimen not analyzed	Wrong test reported
Wrong patient identification	Specimen misplaced	Result delayed
Wrong test specified	Wrong dilution	Results not ready
Incorrect sample	Quality control failure	Conflicting results
Unsuitable sample	Wrong value	Transcription errors
Wrong container	Instrument failure	Calculation errors
Wrong labeling	Protocol not followed	Results lost
Wrong patient	Wrong analysis	Wrong destination

The common practice of discarding outliers in statistical data obscures the role of mistakes in conformance quality. Even if the frequency of mistakes could be predicted statistically, these methods are useless in predicting when the mistakes would occur. Consequently, even though statistical methods are useful in controlling variation, they are completely ineffective in eliminating mistakes. This limitation of SQC methods applies as much in the clinical laboratory as it does in any industrial setting.

MISTAKE-PROOFING AND SOURCE INSPECTION

In a sharp departure from traditional quality-control methods, Toyota has shown that virtually every mistake can be controlled. However, to control mistakes, Shingo *[15]* recognized that quality-control methods had to change dramatically. Because of the rare nature of mistakes, they can be controlled only with 100% inspection.

At first glance, the 100% inspection methods developed by Toyota seem to be unnecessarily expensive and counter to the sampling methods of SQC. However, Shingo recognized that mistakes cannot be detected and corrected by any other means. If 100% inspections are to be made possible, they must be inexpensive. Also, the inspection methods focus on detecting defect-causing conditions upstream of the process and correcting mistakes before they result in nonconformities. Shingo referred to these upstream inspections as source inspection *[15]*. Shingo was also the first to characterize the differences between judgment, SQC, and source inspections *[15]*. Figure 3 shows the timing and decisions involved in mistake-proofing and source inspection.

A simple example illustrates how different SQC and source inspections are. With SQC, a mixing process could be controlled by measurements, such as pH, taken downstream of the operation. SQC control charts could be used to determine whether the process was in control and would alert the operator when corrective action was necessary. In contrast, source inspection may rely on unique container interfaces to assure that only the correct chemicals can be used in a process. Kits, checklists, or sensors may be used to guarantee that each chemical is added in the proper sequence. Prepackaged quantities and mistake-proof dispensers would prevent the insertion of inappropriate quantities. If the operator tries to remove the mixture before adding all of the necessary chemicals, or before completing the required mixing process, an alarm could sound. With this approach, error-free product would be virtually assured and downstream measurements of the pH would be eliminated.

Mistake-proofing concepts are incredibly varied and must be adapted to each specific problem. Mistake-proofing can involve plausibility checks or redundant but controlling testing, among other techniques. Although mistake-proofing may involve the application of many simple fail-safe mechanisms, costlier traditional inspection activities, when properly implemented, decrease.

Opportunities for applying source inspection. One problem recently discussed at the Clinical Chemistry Forum held in 1996 at San Francisco demonstrates the potential power of source inspection. Batch-to-batch differences in reagent materials used to calibrate laboratory equipment have been observed in clinical chemistry laboratories. A key point is that the these differences are being discovered by the clinical laboratories with judgment inspection methods at a point in the process when the conditions that caused the problem can no longer be controlled. As a result of the differences in reagent batches, the fraction of individuals who are subjected to additional medical evaluations may change dramatically. Unnecessary tests that impose financial and emotional burdens, and often physical discomfort, on patients could be avoided.

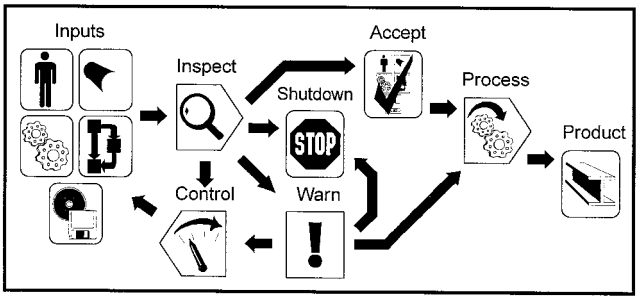

Fig. 3. Source inspections verify that all of the inputs to a process are acceptable before the process is executed.

If any of the inputs are not correct or if any mistakes have been made in the setup, action to stop, warn, or control the inputs is taken before the process is executed. When the inputs are accepted, the process is executed without the need for downstream inspection.

Let us examine a few simple ways to move inspection progressively closer to the source to eliminate the problem caused by differences in reagent batches. A representative of one manufacturer of reagent materials pointed out that poorly controlled storage and transportation temperatures may be a key source of the observed differences. To reduce the likelihood of improper storage, the clinical laboratory's storage could be mistake-proofed. In addition, the storage equipment should be properly maintained with backup power to preclude out-of-tolerance storage conditions.

New reagent batches, as delivered to the customer, may be substantially different from previous batches. Laboratories should not wait until the old batch is depleted to discover such differences. The laboratory could require that the manufacturer supply with each shipment a small vial or packet of the reagent material. This specimen would be used as soon as it is received in a back-to-back calibration comparison with the old batch currently in use. This would allow the laboratory to identify major differences in batches in time to take corrective measures. These checks would naturally be eliminated as soon as the laboratory gained confidence that they were receiving and maintaining reagents with consistent properties.

Because the laboratories probably are not receiving reagents with consistent properties, inspection should be pushed further upstream where the problems occur. The most likely cause of batch-to-batch variation may be inadequate temperature control during shipment. Inexpensive thermal tags that permanently change appearance if temperature limits are exceeded could be used on all shipping containers. Because the carrier would be liable for inadequate temperature control during transportation, the tags would encourage more care on the part of the carriers, while giving the customer a positive indicator showing whether the product has been handled properly in transit. It would be better still to mistake-proof the thermal control during transportation.

Mistake-proofing the transportation will not solve the problem if the supplier ships material that is not consistent. Reagent inconsistency may be the result of mistakes in the batch-to-batch setup during manufacturing or variation in the raw materials received from their suppliers. Mistake-proofing can minimize these differences throughout the production–supplier systems. Manufacturers could also mistake-proof storage and manufacturing processes. Thus, mistake-proofing the suppliers may represent the ultimate source inspection. At an even more fundamental stage, it may be possible to reduce the susceptibility of the reagent materials to thermal variations and aging.

As shown by the example, the inspection methods can be changed to move progressively from late discovery of a problem to its earlier discovery and then to problem prevention. We must continually strive to move the inspection further upstream until we detect and control conditions before they cause nonconforming products. The highest degrees of quality can be achieved only when inspection controls the source of the problem rather than detecting the result of inadequate control.

RELATIVE EFFECTIVENESS OF QUALITY-CONTROL METHODS

Figure 4 shows an approximate relative comparison of the performance of various quality-control methods based on data we have collected from a broad range of companies. Typical nonconformity rates are 2000 to 20 000 ppm with SQC (although many exceptions above and below this have been observed). Data provided to us by Motorola *[8]* suggest that nonconformity rates are ~1000 ppm by Motorola's Six Sigma. A recent proprietary benchmarking study showed that the quality-control costs, including the cost of scrap, rework, and repair are ~6% to 24% of the total production expenses for US companies. This study included quality leaders using Six Sigma or other SQC methods.

Several independent sources have indicated that Toyota and its suppliers consistently maintain nonconformity rates <50 ppm. The proprietary benchmarking study showed that Toyota achieves this high degree of quality while spending <3% of its total production budget on quality-control–related factors. Unlike most automotive manufacturers, Toyota needs virtually no rework at the end of its production lines, yet the company consistently has the highest customer quality ratings.

The effectiveness of Toyota's quality-control methods has been independently confirmed in many industrial settings. Using mistake-proofing methods on manual pick-and-place packaging and assembly, Stark Manufacturing, Inc. *[16]*, reduced nonconformities from 800 ppm to <5 ppm over a 4-year period. In addition to virtually eliminating nonconformities, their experience suggests that mistake-proofing has roughly doubled the productivity of the operations where it is applied. Supporting the effectiveness of these methods, a recent article, "Toyota Road USA," published in *TIME [17]*, stated that one US

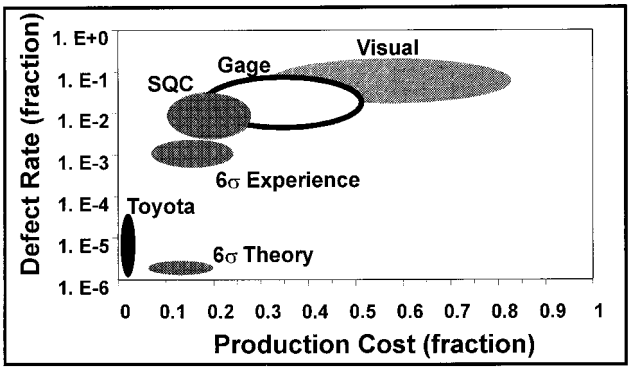

Fig. 4. An approximate relative comparison between the fraction of production cost spent on quality-control factors and defect rates achieved by various quality-control methods.

supplier for Toyota had produced 60 000 parts before they observed their first defect (17 ppm), an incredibly low defect rate for the manufacturing start-up of a new product. Given the gradual reduction in nonconformities achieved over decades of quality-control improvement, the impact of Shingo's quality-control methods are singularly remarkable.

controlling complexity

Another source of nonconformities is complexity. As the difficulty of a task decreases, fewer opportunities arise for mistakes and excessive variation. Consequently, the number of nonconformities per product can be reduced by simplifying or eliminating tasks required to produce a product. Substantiating this intuitively sound trend, our research has shown that nonconformity rates in the manufacturing environment are highly correlated with a measure of assembly complexity *[8]* determined by design-for-assembly techniques. Without requiring a detailed understanding of this relationship, the important consequence is that quality is linked to the time and difficulty required to perform any task. With careful planning, the difficulty of executing virtually any process can typically be cut in half *[18, 19]*. The two immediate benefits are improved productivity and improved quality.

Tasks are easier to perform when reach distances are minimized and when parts are easy to pick up, align, and assemble. The difficulty of handling parts is reduced when product design prevents incorrect assembly, or inadvertent combinations of wrong materials. Workers can make decisions more quickly with fewer errors when they are guided by kits that direct the sequence of their activities or by visual clues, like lights that turn on to indicate the appropriate selection. Improving visual and physical access during the execution of a task makes it easier. Information necessary to perform a task should be clear, easy to read, and unambiguous. Such improvements illustrate only a few of the many ways in which processes can be changed to reduce their complexity.

anticipate and eliminate nonconformities

Just as source inspection strives to prevent nonconformities rather than detect them, the best way to achieve quality is to anticipate and prevent quality problems rather than to wait until the problems show up in production or in the laboratory. This requires careful planning at the earliest stages of product and process development. Our experience suggests that quality improvement efforts are most effective and efficient if addressed in the following order: Step 1, thoroughly investigate the product or process to identify opportunities for simplification; Step 2, simplify the product or process; Step 3, identify the mistakes that are most likely to occur, and define the mistake-proofing methods; Step 4, identify additional opportunities for source inspection and define source inspection methods; Step 5, select the variation control philosophy (SQC or Six Sigma). Establish tolerance and control limits for the product or process. Select equipment and (or) techniques capable of achieving the required tolerances limits, and define the procedures for controlling variation.

This defined order for addressing conformance quality minimizes design iterations. By first focusing on simplifying the product or process, mistake-proofing is easier. Mistake-proofing and source inspection can often replace variation-control methods while achieving better results at a lower cost. Thus, mistake-proofing and source inspection opportunities should be identified before defining the variation-control methods.

The preceding steps must often be applied several times throughout the development of a product or process. At the earliest stage, these steps should be applied to prevent incorrect operation or execution by the end user. For example, the design of new laboratory equipment should first address ease of operation and mistake-proof controls. Next, the fabrication and assembly of such laboratory equipment should be designed to be simple and mistake-proof. The production process and equipment should also be simplified and mistake-proofed to minimize manufacturing nonconformities. Finally, the end users must mistake-proof their laboratory setup and simplify the flow of materials in their facility. The highest degree of quality can be achieved only if the full spectrum of these quality issues are addressed at every stage of design, production, and use.

Quality—A Cultural Change

Thus far, we have focused on the technical aspects of achieving the highest degree of quality control. However, improving quality is as much a cultural and social change as a change in technology. To overcome some of the common barriers to quality improvement, some fundamental principles should always be kept in mind.

Focus on results [5]. If you want to reduce nonconformities, measure and track the reduction in nonconformities. Too often organizations try to assess the effectiveness of their quality-control programs by measuring such factors as the number of people trained or the number of new quality teams, only to find little progress in reducing the number of nonconformities.

Stop blaming employees for mistakes. Employees blamed for mistakes conceal rather than control them. In such an environment, it is impossible to effectively implement mistake-proofing. Rather than blame workers, we should recognize that we all make mistakes and that it is management's responsibility to teach and implement mistake-proofing. This requires a cultural change, because we traditionally view mistakes as a form of negligence.

Invest to prevent rather than correct nonconformance. The cost of preventing problems is a small fraction of what must be spent to correct problems after they have been occurred.

Quality is in the process or product, not in the documentation. Many companies have excellent documentation of poor quality. On the other hand, when an effective mistake-proofing program is implemented, outstanding quality can often be achieved with little or no documentation. This is the ideal every company should strive for.

The barriers to implementing mistake-proofing are increased by the mental association with fool-proofing, and no one wants to be thought of as a fool. Only when workers participate in mistake-proofing their own working environment and begin to see the profound benefits of these techniques will their attitudes change.

Conclusions

In spite of substantial advancements in quality control, we have historically viewed nonconformities as an inevitable part of every process that cannot be entirely eliminated. This view is strongly influenced by the perception that variation, the primary source of nonconformities, can be best controlled with inspections that are downstream of the process. Such inspections, even with feedback control, will never be able to prevent, detect, or correct every nonconformity. As shown here, a critical limitation of the SQC-based methods is that they are ineffective in detecting and controlling mistakes, the dominant source of nonconformities in most organizations today.

In contrast, the source inspection techniques developed by Shingo *[15]* focus on detecting and correcting conditions that could cause nonconformities before the execution of a process. These source inspection methods, which rely heavily on 100% inspection and mistake-proofing, can prevent virtually every nonconformity at a fraction of the cost of traditional SQC-derived methods. Organizations that have aggressively implemented these techniques have achieved remarkably low defect rates, often operating for months without a single detected nonconformity.

Because complexity contributes to both excessive variation and mistakes, eliminating unnecessary complexity is a key element of the most effective quality-control methods. Efforts to reduce complexity have the dual benefit of reducing nonconformities while improving productivity. The link between complexity and nonconformity reinforces the need to anticipate and eliminate opportunities for error at the earliest stages of product and process planning.

Lapworth and Teal *[12]* stated in 1994 that "Despite passing interest during each of the three last decades in 'blunders' occurring in clinical laboratories, the situation remains as Northam described it in 1977, namely that 'although much effort and expense is being devoted to the assessment of analytical variation, little attention has been directed to the detection of laboratory blunders'." Rather than merely detecting mistakes, the time has come when we can and must begin to prevent mistakes in the clinical laboratory setting by applying the concepts of Shigeo Shingo. Laboratories that lead in this effort will have the opportunity to improve productivity, decrease waste, and increase customer loyalty, while reducing exposure to potentially costly litigation.

References

1. Nikkan Kogyo Shimbun, Ltd., ed. Poka-yoke: improving product quality by preventing defects. Cambridge, MA: Productivity Press, 1988:1–28.
2. Womack JP, Jones DT, Roos D. The machine that changed the world. New York: Rawson Associates, 1990;93–6.
3. Juran JM, Gryna FM, eds. Juran's quality control handbook, 4th ed. New York: McGraw-Hill, 1988:24.3.
4. Deming WE. Out of crisis. Cambridge, MA: MIT Center for Advanced Engineering Study, 1986;314–6.
5. Total quality management—variability reduction: tools for implementation. Dearborn, MI: American Supplier Institute, 1988;1–9.
6. Schaffer RH, Thomson HA. Successful change programs begin with results. Harv Bus Rev, Jan.–Feb., 1992;70:80–9.
7. Harry MJ, Stewart R. Six sigma mechanical design tolerancing. Publication 6s-2-10/88. Scottsdale, AZ: Motorola, 1988.
8. Hinckley CM, Barkan P. The role of variation, mistakes, and complexity in producing nonconformities. J Qual Technol 1995;27: 242–9.
9. Rook LW Jr. Motivation and human error. SC-TM 65-135. Albuquerque, NM: Sandia National Labs., 1965:5.
10. Rook LW Jr. Reduction of human error in production. SCTM 93-62(14). Albuquerque, NM: Sandia National Labs., 1962.
11. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events. JAMA 1995;274:29–34.
12. Lapworth R, Teal TK. Laboratory blunders revisited. Ann Clin Biochem 1994;31:78–84.
13. Boone DJ. Comment on "Random errors in haematology tests." Clin Lab Haematol 1990;12(Suppl 1):169–70.
14. Pellar TG, Ward PJ, Tuckerman JF, Henderson AR. The Freckle Plot (daily turnaround time chart): a technique for timely and effective quality improvement of test turnaround times. Clin Chem 1991; 39:1055–9.
15. Shingo S. Zero quality control: source inspection and the poka-yoke system. Cambridge, MA: Productivity Press, 1986:1–60.
16. Champions of Industry—Stark Manufacturing [Video]. Richardson, TX: Criterion Productions, 1996.
17. Greenwald J. Toyota road USA. TIME 1996;148:17:72–4..
18. Hinckley CM. A global conformance quality model: a new strategic tool for minimizing defects caused by variation, error, and complexity [ME dissertation]. Stanford, CA: Stanford University, 1993: 80.
19. Watson RG, Theis EM, Janek RS. Mechanical equipment design for simplicity. AT&T Tech J Design for X, 1990;69:14–27.