

## **How to Integrate ISO 9000 Standard in to a Continuous Improvement Process**

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### **INTRODUCTION**

Our goal is to continuously improve quality and remain competitive in the world markets. To do this effectively, we must produce and deliver products and services satisfactorily in accordance with the world standards every time as judged by the customers. We must clearly understand why and extent to which ISO 9000 bears relationship with this objective. Having done that we are then in position to design a quality system that integrates continuous quality improvement in all ISO 9000 elements.

### **WHAT DOES ISO 9000 PRIMARILY ADDRESS?**

We must divide the gap between the world quality standards and the present company performance in three segments: The gap between world standards and company standards, the gap between produced quality and delivered quality, and the gap between what is promised and what is actually delivered. ISO 9000 quality systems standards are primarily designed to affect the last segment, that is, a gap between what is promised and what is actually delivered. They bear very little and indirect relationship to produced quality and practically no relationship to the world-standards gap.

Issues related to delivered quality primarily focus on preventing the downstream travel of unacceptable products. When these issues are addressed by a well-designed system, the downstream user and the subsequent end user will benefit from this system. Regardless of the level of produced quality, it is possible to design a quality system in conformance to the ISO 9000 standards, and deliver excellent quality. The ever-haunting question is: who pays for the loss generated due to the difference between delivered quality and produced quality. The answer is obvious: customers. The challenge then is how to design a quality system to get close to the issues concerning produced quality.

The second issue is concerning the gap between world standards and the company standards. This gap is referred to as **GRADE OF QUALITY** gap. Suppose a company is producing engines in conformance with the customer's noise and emission standards. This company is also registered as meeting ISO 9000 quality requirements. Let us say that the company gets a chance to bid for the engines required by another country. The company discovers at this meeting that the engine noise and emission standards, which are perfectly acceptable to one customer, are not acceptable to the world. Entering a meeting feeling like a world-class player and discovering that you have to pack your bags

to return home is not exactly what company had in mind in pursuing the ISO 9000. Why not recognize this gap while preparing to earn the ISO 9000 status?

### **WHAT IS REQUIRED TO IMPROVE PRODUCED QUALITY?**

Improving produced quality requires competence in subject matter, knowledge of statistical science, and teamwork to look at the complex yield problems. ISO 9000 auditor is neither expected to be competent in the subject-matter knowledge nor is he or she likely to be. *The standards themselves call for auditing the system elements not the competence level.* Many people argue that CORRECTIVE ACTION ELEMENT of the ISO 9000 standards is designed to improve produced quality. This is not entirely true. Let us examine why.

The distance between produced quality and delivered quality is due mainly to three scientific problem conditions. These can be described in statistical language as: (1) instability, (2) variation, and (3) off-target. These can be translated in engineering language as: (1) problems arising from operational disturbances, (2) problems arising from lack of understanding the present process, and (3) problems arising from the inadequacies in process design. ISO 9000 standards are designed to address the first category only. Well-designed quality system in conformance with ISO 9000 will expose categories 2 and 3 problems, but will generate no solutions. In general, more than 85% problems arising in any system are due to categories 2 and 3, and 15% or less are attributable to category 1. Thus, ISO 9000, by design, can only address maximum of 15% problems. Even category 1 can be challenging to tackle. If we subdivide the problems in category 1, we discover that the operational disturbances causing instability problems may be known or unknown. Well-designed quality system can only address the known operational disturbances. To discover unknown disturbances, we once again need competence in subject-matter, knowledge of statistical science, and teamwork. Thus, ISO 9000 system can only penetrate a portion of the problems in category 1.

Let us now discuss how well ISO 9000 is conceived to solve known operational disturbances. The disturbances can be solved either by written procedures, appropriate documentation, and control signatures; or by use of technology and innovations. By design, ISO 9000 emphasizes procedures, documentation, and signatures. Thus, it indirectly diverts the attention from the use of technology to solve problems.

### **WHAT IS REQUIRED TO IMPROVE A GRADE OF QUALITY?**

A scientific research as well as the understanding of responsibility toward the society in which we live can improve the grade of quality. Let us refer to our earlier example of an engine that met the local noise and emission standards, but did not meet the world standards. Any company that successfully sells noisy and polluting engines to

the local market obviously has not kept up with the world. Not only that the company has been short-changing her own citizens. Why would world want noisy and polluting engines from the ISO 9000 registered company? Without the investment in basic research as well as understanding of the social responsibility, it is not possible to improve grade of quality.

## **HOW DO WE GO ABOUT IMPROVING PRODUCED QUALITY AND GRADE OF QUALITY?**

Based on the preceding discussion, we can appreciate the challenge involved in designing a quality system that can effectively address the issues concerning produced quality as well as achieving world-class status.

Basically there are two options available when a company decides to consider ISO 9000 registration. Either design a quality system that primarily addresses the issues relating to delivered quality and accept improvement in produced quality and grade of quality as incidentals. This is considered to be an easy route.

Or design a quality system that focuses on the issues related to produced quality and continuously improves the performance toward meeting the world standards. This is considered to be a hard route. Our discussion will now focus on how to do the latter. Figure 1 depicts what ISO 9000 explicitly does and does not address.

The focus on world-class status requires that we talk about improvement in totality. This task requires us to address: specification gap between world standards and company/customer standards, variation and off-target problems, solution of instabilities due to unknown disturbances, and use of technology and innovation in curbing the known disturbances. Additionally, it requires us to address productivity and waste issues. We must integrate these ideas into the design of the quality system without violating ISO 9000 framework. Once these ideas are written as a part of the company quality system, they can then be included as a part of ISO 9000 assessment.

Philosophically, we set out to perform the integration task by assigning the responsibility of each of the ISO 9000 elements directly to authorities that influence the outcome. This assignment is a strong motivator to improve, because failure to achieve ISO 9000 will pinpoint a respective authority in charge. Secondly, we add the clauses that integrate the proposed improvement ideas with the caution that they do not violate the scope of ISO 9000 elements. In other words, we enhance the scope of ISO 9000. Thus, the two fundamental ideas in designing the quality system are a) assignment of direct responsibility, and b) clauses that require produced quality and grade of quality issues to be addressed.

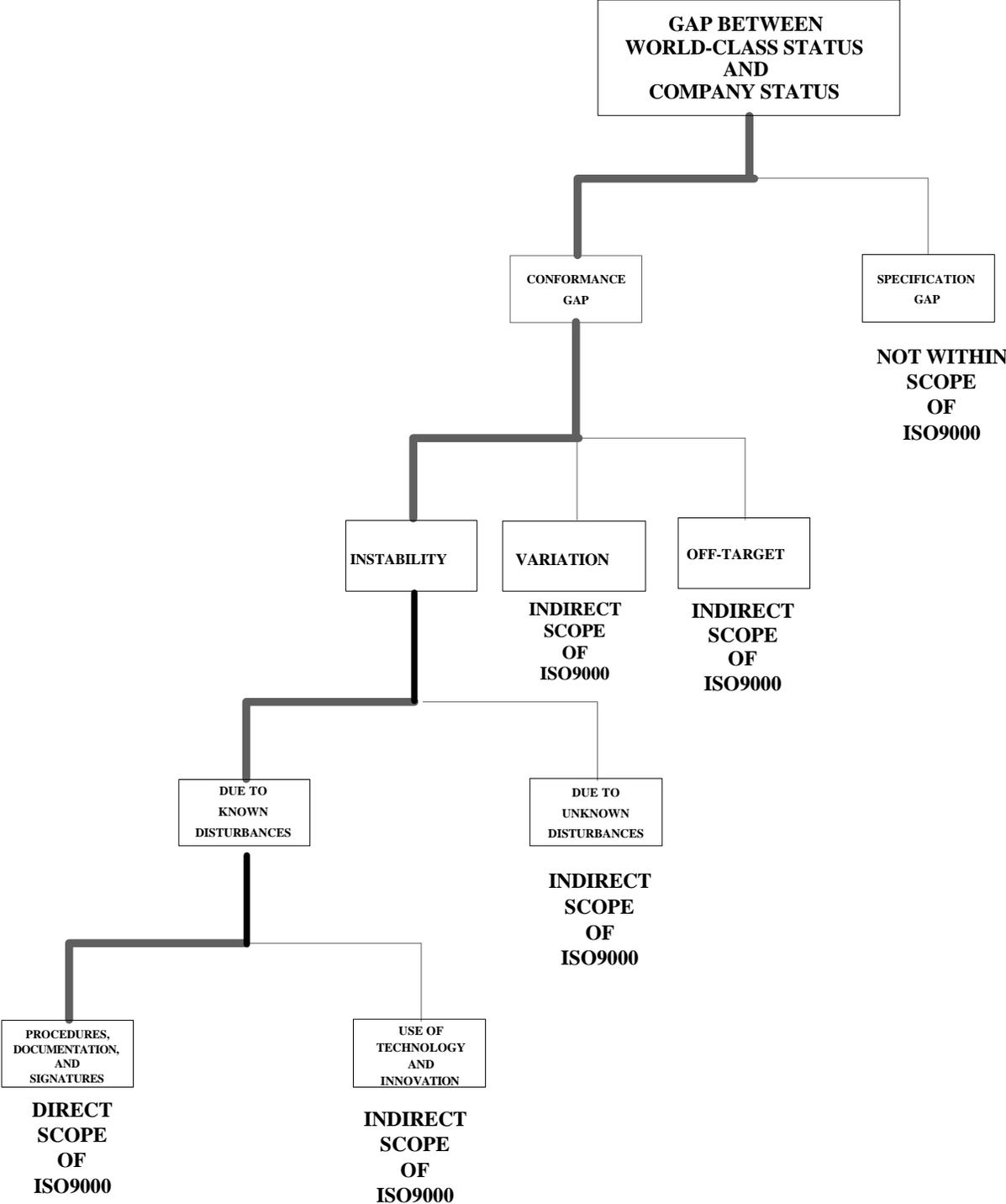


Figure 1 - Direct and indirect scope of ISO 9000 standards

## DETAILS OF IMPROVEMENT CLAUSES AND THEIR OBJECTIVES

The following is the list of clauses that must be added in each element along with their objectives.

### 1. Design control

**Clause:** The design specifications will list the world competitive standards as well as company/customer standards. The gap between the two will be a part of the design review process. The design-engineering department will have a direct responsibility for this.

*Objective:* *To be aware of the specification gaps and of the markets that the company serves.*

**Clause:** The design specifications will include reliability (R) and maintainability (M) specifications.

*Objective:* *To encourage design engineering based on a life cycle costing concept of owning a product over the initial product pricing.*

### 2. Servicing

**Clause:** The servicing records will maintain # of backlog orders, first-time fixed success rate, response time, and customer complaints. The servicing department will have a direct responsibility for maintaining and improving these indexes.

*Objective:* *To continue providing support in a cost-effective manner during the ownership of the product.*

### 3. Management responsibility

**Clause:** Management will address the gaps between the world standards and the current standards.

*Objective:* *To keep management fully aware about the specification gaps and to generate actions to close the gaps.*

**Clause:** Management problem reporting will be in three categories: instability, variation, and off-target for three types of problems: quality, productivity, and waste.

*Objective:* *To focus on all problems not just the instabilities that affect quality.*

### 4. Contract review

**Clause:** Contract review will include the first run capability numbers. First run capability will be reported either as an output to input ratio of

material weight or the number of units. The design department will have a direct responsibility for producing this information.

*Objective: To make it visible that the first run capability almost never produces 100% yield, to know yield level in early stages, and to keep continuous focus on increasing the yield.*

5. Purchasing

**Clause:** Purchasing will report on-time delivery performance as well as number of shipments accepted with no complaints. Purchasing will have a direct responsibility for producing this information.

*Objective: To choose the fittest suppliers by preventing a selection based on trade-off between price and quality-productivity.*

**Clause:** Purchasing will also maintain time segments from material ordered to the invoices paid as a fair treatment of the suppliers. These data will be compared with the world standards and presented for management review and actions.

*Objective: To treat suppliers as equal partners.*

6. Purchaser supplied product

**Clause:** Purchaser supplied product will be treated same as the supplied product. If there are any exceptions, they will be accepted in writing carrying a signature of the customer representative. All complaints directly related to the purchaser supplied product will be reported to at least two parties at the customer location: supplying party and receiving party.

*Objective: To prevent the abuse of the captive situation.*

**Clause:** Any special system to be designed to deal with the purchaser supplied product is the direct responsibility of the purchasing department.

*Objective: To prevent quality related problems being dumped on production or quality control department.*

7. Process control

**Clause:** Process controls will be identified in three categories: deterministic controls, statistical controls, and product controls. These controls are the direct responsibility of process engineering. An assistance

may be taken from quality engineering in designing effective statistical controls and product controls.

*Objective: To encourage use of all three forms of controls during the planning process. Process engineers are well-versed with deterministic controls. Statistical controls and product controls are treated only as incidentals.*

8. Corrective action

**Clause:** Corrective actions will be applied to quality, productivity, and waste problems. Corrective actions will be reported for three different categories of problems: instability, variation, and off-target. Corrective actions will be described in two categories: investigation required or action needed. Action category will be subdivided into two categories: procedures, documentation, signature solution or technology solution. The cost-effectiveness of ultimate choice will be explained.

*Objective: To encourage use of technology and innovations in solving all types of problems. To emphasize that procedures do not equal competence and/or excellence.*

9. Internal quality audits

**Clause:** Number of repeat offenses will be reported.

*Objective: To redirect auditing energy into problem-solving when there are large number of repeat offenses. Many companies spend large amount of time in auditing even when problems are chronic and well known.*

10. Quality system

**Clause:** A system that will identify how the balance is maintained between process controls and product controls.

*Objective: To assure that system is not designed heavily in favor of product controls. In a well-designed quality system, there is a continuous and systematic move from product control to process control.*

**Clause:** A system that will be responsive to all types of problems directly or indirectly connected to quality, productivity, or waste.

*Objective: To prevent quality improvement by decreasing productivity and/or increasing waste.*

11. Document control

Clause: Each department is individually responsible for maintaining its document control. Internal independent audits will be conducted to assure that this responsibility is executed as intended.

*Objective: To prevent quality department from becoming a hoarder of all the papers.*

12. Product identification and traceability

No changes are recommended in this element.

13. Inspection and testing

No changes are recommended in this element.

14. Inspection, measuring, and test equipment

No changes are recommended in this element.

15. Inspection and test status

No changes are recommended in this element.

16. Control of nonconforming product

Clause: Nonconformance will be reported in rework, scrap, and returns categories. Any associated productivity loss will also be reported. Production department has a direct responsibility to generate this information.

*Objective: To prevent manipulation of indexes to create an illusion of improvement. When nonconformance truly improves all indexes must show improvement.*

17. Handling, storage, packaging, and delivery

Clause: The assigned authority will report Problems or complaints in each category.

*Objective: To treat handling, storage, packaging, and delivery as processes just the same as design, production, and purchasing processes. Many times problems in these categories are just as serious as any other categories.*

18. Quality records

Clause: Each department is individually responsible for maintaining its own records, retention schedules, authority signatures, and periodic verification. Internal independent audits will be conducted to assure that this responsibility is executed as intended.

*Objective: To prevent this responsibility being dumped on the quality department. The quality department cannot be a judge in every case to determine the implication of record related problems.*

19. Training

Clause: Human resource department is responsible for developing training needs and status. The HRD department may work with other departments to create a need list. The categories may include job content, safety, quality, and other aspects to minimize quality, productivity, and waste related problems.

*Objective: To prevent helter-skelter training approaches where attending training is more of a perk than a meaningful investment. Many training programs are brought into the company not with any need analysis but because a member of the management team attended some airport seminar that he or she liked.*

Clause: HRD department will report the attendance at the training meeting. The records will show the actual hours attended by the employee and not the scheduled hours.

*Objective: To prevent the abuse that is prevalent in many training sessions where employees go in-and-out at free will with no accountability for what they learned.*

20. Statistical techniques

Clause: Use of statistical techniques will be reported in three categories: product control use, process control use, and problem-solving use.

*Objective: To encourage utilization of powerful statistical techniques. Some complex problems can only become solvable with statistical techniques.*

## SUMMARY

There has been an explosive interest throughout the world in achieving ISO 9000 certified status to claim a world-class quality status and to participate in the business

opportunities in international arena. Somehow ISO 9000 quality standards are perceived to be instrumental in closing the gap between company's current performance and the world-class quality standards. Those companies who believe this to be true are misguided. A closer examination of the quality gap reveals that there is a gap of promise versus delivered, there is a gap of what is produced and what is delivered, and there is a gap between the worlds standards and company's current standards. ISO 9000 is primarily designed to address the gap between what is promised and what is delivered. ISO 9000 only indirectly touches the area of produced quality and does not touch the area of world specification standards at all.

It is possible, however, to design a quality system which can address all three segments of quality gap within the framework proposed by ISO 9000 standards. Those companies who wish to achieve ISO 9000 as a marketing instrument are likely to take a short-cut and design a system that delivers what is promised. On the other hand, the companies truly desirous of achieving world-class status will recognize the investments to be made in competence, technology, and research. To do this systematically and continuously, they are likely to design their quality systems such that they will earn world-class status with world-class quality and not with paper procedures.

I conclude with the opinion that more than 80% of the companies have earned ISO 9000 status with written procedures than any significant change in their quality or their world-class status. This paper offers the argument and approach to make continuous improvement integral to quality systems. Who said Pareto does not work. He always does.