

ISO 9001: Nonconformities, Corrections and Focus



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In the last edition of the Newsletter, we listed the topics of the "ISO Team" series for 2004. We also asked for any additional subjects that you, our readers, would like us to cover. The response was a list of concerns from ISO 9001 teams throughout the country. The topics that we were asked to incorporate included:

- Human resources
- Corrective Action
- Preventive Action
- Customer focus
- Goals and objectives
- Planning audits of processes

Thank you for the suggestions. Some of your comments show that many ISO Teams are not satisfied with gaining or keeping Certification. They are trying hard to make their systems effective business tools.

"The reasonable man adapts himself to the world.

The unreasonable one persists in trying to adapt the world to himself.

Therefore all progress depends on the unreasonable man."

George Bernard Shaw



NONCONFORMITIES

A frequent complaint heard from ISO Teams during our Continual Improvement Workshops is that they feel the need to "do Corrective Actions" because the Certification Auditor expects to find them.

When the main reason for a Corrective Action is satisfying the needs of an auditor, it is frustrating for the ISO Team. The whole process is annoying for those affected by the search for a nonconformity needed to justify the Corrective Action.

The ISO 9000 Standard addresses nonconformities in the following way:

■ "A *nonconformity* is the non-fulfillment of a requirement."

■ "A *requirement* is a need or expectation that is stated, generally implied or obligatory."

If a need or expectation is *stated, or obligatory*, it is usually easy to decide when a nonconformity has occurred.

If a need or expectation is "*generally implied*" things can get ugly.

When an ISO Team is using the Standard to make a value added contribution to the organization, it must consider every activity (process) at two levels.

■ Does the activity conform to the requirements of the Standard?

■ Does the activity contribute to meeting the objectives of the organization?

For example, during discussions in our ISO Team Workshops, we find that the Return Material Authorization (RMA) process can be a tricky activity to evaluate.

If we review an RMA process, we are liable to find:

On the surface, everything is fine.

■ Internal Audits confirm that the RMA process complies with the Standard.

■ People understand the process.

■ There is evidence that the process is being followed, the right forms are used and records are kept.

In spite of this, the activity sometimes brings unexpected results.

Let's look at one of these situations.

This is a company in which the *implied requirement* is that "the customer is always right."

Because of this *implied requirement*, it is sometimes easier to authorize a return than to argue with the sales department.

Working with the company, we traced the history of an RMA that was generally accepted as being wrongly issued.

The direct cost to the company of this RMA was around \$25,000.

This was obviously an unhealthy situation that should not be repeated.

In trying to identify why this situation had occurred, we came up with the following choices:

■ Option 1: There was no nonconformity.

There was nothing wrong with the product, so there could be no complaint regarding product realization.

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The customer was happy (probably an understatement), so expectations for customer satisfaction had been met. Yet with no nonconformity, the company lost a minimum of \$25,000. That couldn't be right. So we tried again.

Option 2: This event was the result of a clash of corporate requirements. This is how it happened:

In the blue corner, we had the company's *process guidelines*. If these guidelines had been strictly followed, an RMA would not have been issued.

In the red corner, we had one of the company's *generally implied* requirements. This requirement was to "keep the customer happy."

When the bell rang, the *process* and the *generally implied requirement* met in the middle of the ring, and only one could be the winner.

The referee for this bout (the person issuing the RMA) had no rulebook regarding how to set priorities when two requirements collide. So, he made his own rulebook.

"Keep the customer happy" won.

In this instance, responsible and competent people, confused by a conflict between stated and implied requirements, made a well-meaning decision regarding priorities. As a result, the company suffered. Even though it was understood that a waste of \$25,000 indicated that something was wrong, no nonconformity had been reported and no Corrective Action had been implemented.

For an ISO Team to deal with this sort of situation, it is useful to have a checklist. This checklist will help identify the nonconformity in a factual, logical manner. The checklist is a live document that should be adapted after new experience.

In our RMA example, the checklist could have helped in the following way:

Has the activity disregarded a Clause of the Standard? **No**

Has one of the company's goals been ignored? **Yes** for the stated requirement (follow the process), **No** for the implied requirement (keep the customer happy)

Are there conflicting requirements between the Standard and the process? **No**

Is there a conflict between stated and implied requirements? **Yes**

Is what happened outside the scope of the process? **No**

If you go through this sort of process, it is possible to make a factual evaluation of the event and come to a justifiable conclusion (in this case, a conflict between stated and implied requirements). The result will then be a meaningful Corrective Action that is a value added activity for the company.

"A person who has made a mistake and doesn't correct it is making another mistake"

Confucius



CORRECTIVE ACTIONS

Every company that is ISO 9001 certified has a Corrective Action Procedure.

Lots of companies that are ISO 9001 certified have the same Corrective Action Procedure.

People have been bringing these procedures from company to company since the 1987 Standard.

They are also found and copied from various ISO 9000 publications.

In many companies the measure of an effective Corrective Action Procedure is "did it pass the audit?"

Little wonder that some Corrective Actions are ineffective (even though they did "pass the audit").

The Standard says that a Corrective Action "is an action to eliminate the cause of a detected nonconformity."

We have looked at an example of "detecting a nonconformity". Now let's look at correcting nonconformities.

A Corrective Action means change.

QRC has a successful Change program that is used by companies with mature systems.

The stages of this program are presented below.

If these stages are not addressed in your Corrective Action Procedure, you might want to look again at the Procedure.

① **Know where you are:**

In the RMA example, where you are is a nonconformity caused by conflicting requirements resulting in waste.

② **Establish where you want to be**

Set Objectives for the required change and document these Objectives.

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In the RMA example, the Objectives would include eliminating conflicting requirements.

③ **Assign resources**

Without the proper resources, a Change plan can do as much harm as good.

In the RMA example resources are needed to identify conflicts of stated and implied requirements, resolve the conflicts, document the resolutions and inform people of the changes.

. If insufficient resources are available, the Objectives document has to be changed.
In the RMA example, the objectives could be changed to obtaining management direction when difficulties arise from a conflict of requirements.

. Alternatively, the Change program is postponed or abandoned.
This alternative in the RMA example would be chosen at considerable risk.

④ **Implement effectively**

- . Establish a Plan.
- . Document the Plan to include:
 - A timeline
 - Details of tasks
 - Responsibilities
 - People assignments
 - Training requirements (if any)
 - Material requirements (if any)
- . If the resources are not available to meet the Plan, (e.g. the assigned people are busy on other projects) adjustments are required to the Plan or the resources or even the Objectives.
- . Implement the Plan

⑤ **Know when you have arrived**

You have arrived when the Objectives of the Change have been achieved.

📌 Success is determined by an evaluation of the results of the Change against the requirements of the Objectives.

📌 At an appropriate time, an assessment of the long-term effectiveness of the change is made to insure it is sustainable.

In the RMA example, the assessment would focus on whether people are still confused by conflicting requirements and if there are more examples of waste as a result.

“There is nothing wrong in change if it is in the right direction. To improve is to change, so to be perfect is to have changed often”

Winston Churchill



KNOWING WHERE TO FOCUS

As shown in our RMA example, nonconformities, as defined by the Standard, are not always easy to find. As an ISO 9001 System matures, this situation becomes more prevalent. For example, QRC helps companies maintain their ISO 9001 Systems by conducting their Internal Audits. Over many years of providing this service, we have found a consistent trend. When a company deals effectively with nonconformities, the time we spend on auditing its System gradually decreases, because there are less nonconformities each audit.

If this is what is happening in your organization, where else do you focus to make the Quality Management System a value added asset?

One of the frequent observations made by our Clients about ISO 9000:1994 was that it brought big improvements at the beginning, but, after the first few years, the difference that it made was insignificant.

This was largely because the goal of ISO 9000:1994 was to improve customer satisfaction by removing nonconformities. When you have to search to find a nonconformity to satisfy a Certification Auditor's expectation that you "do Corrective Actions," you are ready to move on to the next stage of maturity of your Quality Management System (see QRC Newsletter 505).

The ISO Team's focus will change from "where are there nonconformities?" to "where are there opportunities for improvement?"

To assist ISO Teams in this task, QRC has developed a simple to use Self-Assessment program. Focused on the quality of deliverables to both internal and external customers, ISO Teams that use the Self-Assessment program never again have to search for opportunities for improvement.

“If you see in any given situation only what everybody else can see, you are as much a victim of your culture as a representative of it”

S. I. Hayakawa