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AQA INTERNATIONAL NEWSLETTER

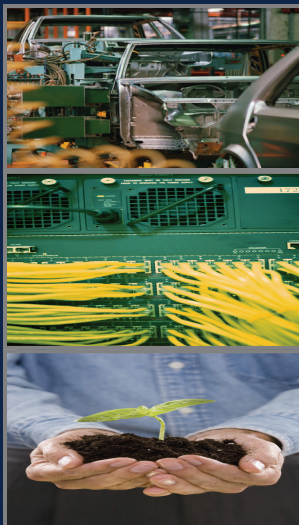
Volume V, Issue VI

June 2010



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Featured Client:



Rathburn Tool & Manufacturing is located in Auburn, IN and has been in business since 1983 when it began producing tooling, fixturing, prototypes and small production machining. Today they have a niche in CNC Production Machining where they are a World Class Global Supplier and use the latest technology available while applying the highest quality standards with a personalized service that produces quality results for better customer satisfaction. With a mission to help enable customers to maintain and enhance their competitive position by providing products and services that represent affordable excellence to both the customer and end users, Rathburn Tool & Manufacturing continually puts their customers first.

To ensure continued growth and improvement in meeting customer needs, Rathburn Tool & Manufacturing maintains a philosophy based upon ethical conduct, teamwork, mutual trust and a fair value. They strive to empower team members through a teamwork approach, encouraging continued education and training as well as giving back to the community through various community partnerships. By encouraging involvement and accountability by all team members in an atmosphere of professionalism, trustworthiness, and integrity, Rathburn Tool & Manufacturing's success has been a combined effort of the capabilities and contributions of all team members.

Rathburn Tool & Manufacturing's machining centers produce accuracy and repeatability consistently to meet the demands of today's highest quality standards. Due to the company's dedication to continuous improvement in total customer satisfaction, their quality system involves every level of employee and every aspect of their business. Equipped with the latest manufacturing technology available to ensure quick turnaround and high quality, Rathburn Tool & Manufacturing's shop features the latest CNC mills and lathes that can be utilized for precision machining of aluminum, cast iron, steel, brass and stainless steel parts. For more information regarding Rathburn Tool & Manufacturing, check out their website at: www.rathburntool.com

Unspoken Miscommunication

Article Written by: Bill McCalla, AQA Auditor

Tacit approval. The word tacit means unspoken. Tacit approval or a nod of the head can lead to misunderstanding. When your child is told "Go ask your father," you then ask "What did they say?" The child responds, "Well they didn't say no." Does this mean they said yes? Did they even ask the other parent? How does this relate to the world of audits? The statement I've heard before is "The customer (or SQE or a previous auditor) accepted this." In reality, the situation is that the customer or SQE did not reject it (yet) or the auditor did not write a nonconformity.

This "tacit" approval does not signify that the process or activity audited is free of nonconformities. Due to random sampling and the particular audit trail followed, time constraints and other factors, everything cannot be covered. How can miscommunication be avoided regarding audit results? Like the child and father example, one outcome doesn't exclude the other. Just because a nonconformity is not written doesn't mean a nonconformity doesn't exist.

To help improve understanding of the status of what is audited, two sets of eyes are on every audit. Besides the auditor, there is always a guide or escort. Do the auditor's guides happen to notice any other issues during the audit that the auditor may have overlooked? Does the audit trail reveal something else that needed to be addressed? Use the time spent with the auditor to take notes on what the auditor is actually reviewing along with other things that may need to be fixed or improved. This will increase the value of the audit.

Meet the Staff:

Originally from Istanbul, Turkey, Ahmet Faruk Taka has been working with AQA 's Turkey office for 10 years. During this time, he has served as an MDD Specialist as well as a QMS and EMS auditor. In May of 2010, Ahmet moved to Columbia, South Carolina with his wife Tuba and son Osman to begin work for AQA USA. He currently holds the position of CE Marking Specialist and is very excited about working with clients to pursue CE product certification. Ahmet's favorite thing about AQA is working with clients and auditors regarding anything and everything having to do with CE Marking for the Medical Device Directive and Pressure Equipment Directive. In his free time, Ahmet enjoys hanging out with his family and fishing. We are very excited to have Ahmet as part of our AQA USA team and sincerely welcome him!



Following Up on Follow-Up Actions

Article Written by: Richard Everhardt, AQA Auditor

How robust is your process for following up on items from previous management reviews? This can be a particularly troublesome area when auditors view your records for compliance. More importantly however, is the problem that this lack of follow-through can be to your management system. Very often follow-up items contain opportunities for the continual improvement of your processes or systems. When these items are not completed you miss these opportunities. While the reasons for the lack of follow-up are many, here are a few guidelines to ensure that these opportunities are completed on a timely basis.

1. **Lack of Tracking System** - Too often these follow-up items are buried within the management review minutes and are too easily overlooked (or forgotten!) when the meeting has ended and the minutes distributed. In your review minutes consider highlighting or listing separately the follow-up items to immediately bring attention to them.
2. **ASAP Deadlines** - Who can respond ASAP? What does ASAP mean? ASAP means different things to different people. To some, as soon as possible never happens due to other responsibilities and assignments that are more critical. To others, as soon as possible indicates a lack of urgency or seriousness due to the lack of a deadline. Instead of this often-used timeline consider setting specific dates when the action must be acted upon or completed. Most people work better when a specific deadline is established.
3. **No Specific Assignee** - As an auditor, I have witnessed many sets of management review minutes that do not assign a follow-up task to one individual, instead assigning it to, for example the "management team". Even if the task is one that the "management team" must complete, it should still be assigned to a project leader or champion for best results. If no one person is assigned the task, there is a strong likelihood that the task will remain undone.
4. **Repetitive Tabling of Items** - Far too often auditors see where the same item is tabled from one management review to another. The problem with this is that the idea or item loses its importance over time. As each review period passes, management review participants can lose the meaning or intent of the item and it simply goes away. Consider a guideline where-in an item can only be tabled a specific number of times before the decision is made to proceed or not.

To increase the likelihood that these follow-up items will be completed on a timely basis consider:

1. **Develop an Action Plan** - An outcome of a follow-up item can be the assignment for the completion of an Action Plan by the assignee. This plan can include a feasibility review, timetable, and proposed budget for the action item being considered. The Action Plan must contain a deadline (such as two weeks after the review) and be submitted to the management representative for tracking purposes. When the next management review occurs, this plan can be reviewed for suitability and a decision made to proceed or not.
2. **Interim Follow-Ups** - This is particularly useful when management reviews are conducted on a quarterly or annual basis. Interim follow-ups can be completed using the action plan and reported to the management representative or to the entire management team. Interim follow-ups keep the item alive and vital.



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Road to European Union Compliance and CE Marking for Pressure Equipment

Article Written by: Ahmet Faruk Taka, AQA CE Marking Specialist

Before the creation of the European Union, nations developed their legislation independently. Once the European Union (EU) was created, in certain areas, state members could not permit into its territory products that were legal elsewhere in the union. The situation is frustrating for manufacturers who have heavily invested in developing a product. Even within the EU, manufacturers were obligated to modify their products for each member state's market.

This was a direct contradiction to the goal whose concept is to facilitate free movement of goods in the internal market while ensuring a high level of protection for customers. To break the barriers of free trade, the EU legislation came up with new approach directives in 1985. The idea was very simple and provided a new concept for achievement. It was basically stated that what is safe (or unsafe) in one country, is also safe (or unsafe) in the other country.

New Approach Directives:

A new approach directive lists issues that are to be addressed by the manufacturer. These clauses are known as Essential Safety Requirements or ESR's. New approach directives are based on the following principles:

- Harmonization of standards limited to essential requirements.
- Only products fulfilling the essential requirements may be placed on the market and put in service.
- Application of harmonized standards or other technical specifications remains voluntary and manufacturers are free to choose any technical solution that provides compliance with essential requirements.
- Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive.

Since 1987, 20 CE directives were adopted on the basis of the new approach and the global approach and have progressively come into force.

Global Approach:

Modular approach provides a template for product legislation directives and consists of three major elements which must be understood when attempting to comply with directives.

- Conformity Assessment Modules
- Notified Bodies
- CE Marking

A module is a technique or procedure by which an assessment is conducted where notified bodies are independent companies appointed by a member state government to perform the third party duties defined in the assessment modules. Having demonstrated the required experience and knowledge, the notified body must show that it can operate an assessment program. This is achieved through the development of a quality system in line with, or formally accredited to the EN 45000 series.

CE Marking:

Once a product has passed through an appropriate assessment module and documentation is completed, it complies with the applicable directive. At this point, the manufacturer affixes the CE marking when approved. The CE marking shows interested parties that the product complies with all applicable directives.