



AQA INTERNATIONAL NEWSLETTER

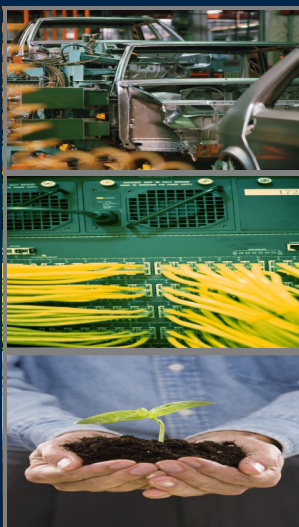
Volume V, Issue XI

November 2010



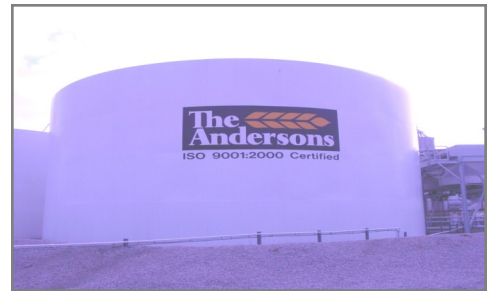
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Featured Client: The Andersons, Inc.

The Andersons, Inc. is a diversified agribusiness and retailing firm based in Maumee, Ohio with interests in the grain, ethanol and plant nutrient sectors of U.S. agriculture. As well as in railcar leasing and repair, turf products production, and general merchandise retailing. Founded in 1947 by Harold Anderson and his family, what began as one grain elevator with 500,000 bushels of storage capacity has now grown into 12 elevators in Ohio, Michigan, Indiana and Illinois, with over 69 million bushels of storage space and state-of-the-art handling and shipping facilities.



The Andersons currently own and operate nine plant nutrient operations with dry and liquid fertilizer storage capacity of more than 550,000 tons. As a commitment to their customers, The Andersons have six liquid fertilizer and industrial product manufacturing plants that are ISO 9001 certified, with the first one registered in 1998. They are a full-line supplier of nitrogen, phosphate, potassium, and compounded fertilizer products—buying, transporting, storing, mixing, bagging, and marketing more than 1 million tons of fertilizer materials to agricultural dealers every year.

With a mission to provide extraordinary service to their customers, help each other improve, support their communities and increase the value of their company, The Andersons places a constant and primary focus on satisfying the needs of their customers. For more information regarding the Andersons, Inc. and the services they provide, be sure to check out their website at the following address: www.andersonsinc.com

Checklist Manifesto

Article Written by: Bill McCalla, AQA Auditor

When you board a plane, often you will hear the alarms and alerts emanating from the cockpit. The cabin crew is going through their pre-flight checklist. Have you ever wondered how that checklist became a mandatory part of every flight?

On October 30, 1935 at Wright Field in Dayton, Ohio, The U.S. Army Air Corps held a flight competition for the military's next long-range bomber. Boeing's new aluminum alloy model 299 surpassed all the competitors' entries. It far exceeded the design specifications, flying faster and twice as far with five times the payload of previous bombers. The small crowd of army brass and manufacturing executives watched as the plane roared down the tarmac, take off and then turn on one wing, stall and then crash in a fiery explosion. An investigation revealed no mechanical flaws. The crash was due to "pilot error". Although the pilot was one of the top test pilots, the new plane with four engines, each with its own fuel-oil mix, new retractable landing gear, electric trim tabs, flaps and hydraulic controls was deemed "too much airplane for one man to fly."

The pilot had forgotten to release a new locking mechanism on the elevator and rudder controls. The result of this competition almost bankrupted Boeing, since the military elected to choose the competitor's inferior plane. Boeing test pilots took this opportunity to decide what needed to be done. Since the pilot killed was the air corps chief of flight testing, more training did not seem to be the logical choice. The ingenious simple answer was the creation of the pilot's checklist. Planes now have become so complex that small, simple index cards listing the routine step by step checks for takeoff, flight, landing and taxiing became necessary. The model 299 went on to fly almost 2 million miles without an accident. The military ultimately ordered almost thirteen thousand of the aircraft, which helped the Allies win World War II as the B-17 Flying Fortress.

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A checklist has become an important tool to address the fallibility of human memory. It is meant to assist someone who is already trained or an expert at what they do. When is a checklist appropriate? Should a checklist be used in internal audits? For many standards, a checklist is a common tool in internal audits, often to keep the auditor from forgetting a clause or a “shall” requirement, but as the audits shift to focus more on process effectiveness, is the continued use of the checklist acceptable? It depends on the expertise of the auditor. The auditor needs to be fully trained so that the checklist as a tool should help those auditors who may be a little “rusty” from infrequent audits. It should provide reminders of what needs to be done or covered and should not be used as a crutch in place of inadequate training or lack of auditing skills. Imagine if your airplane pilot only flew once or twice a year. Would completion of a checklist be enough evidence of an effective pilot? Training or expertise in the activity is necessary before the checklist becomes used as a tool.

For more information on checklists and how the construction industry went to checklists when projects became too complex for a “Master Builder” and how the medical industry is adopting checklists, see the very informative book “The Checklist Manifesto” - “How to Get Things Right” by Atul Gawande.

What is R2/RIOS?

Already e-Stewards accredited, AQA is currently in the process of gaining their R2/RIOS accreditation as well. The terms R2 and RIOS may sound familiar but you still may find yourself wondering just what they mean. Responsible Recycling Practices (R2) were developed over several years by a broad-based stakeholder group for the electronics recycling industry and is promoted by the Institute of Scrap Recycling Industries also known as ISRI. In addition to having a strong, comprehensive Environmental, Health, and Safety Management System (EHSMS) and other controls, R2 requires a recycler to:

- Establish a reuse and recovery hierarchy of responsible materials management.
- Comply with all legal requirements including imports and exports.
- Protect worker health and safety and the environment.
- Manage focus materials (FMs) on site and through selected downstream processors.
- Refurbish and properly test reusable equipment and components.
- Implement accepted data destruction procedures.
- Maintain security measures in all parts of the facility.
- Possess adequate insurance and facility closure plan.

Designed for the recycling industry, the Recycling Industry Operation Standard (RIOS) provides a framework for a comprehensive, integrated management system that includes key operational and continual improvement elements for quality environmental and health and safety performance. RIOS has been accepted as an accredited certification program by the ANSI-ASQ National Accreditation Board (ANAB) and offers electronics recycling companies the vital tools for the following:

- Monitor and improve product quality, increasing customer satisfaction and confidence.
- Keep on top of environmental compliance, decreasing environmental risks and costs.
- Improve health and safety practices, reducing health and safety risks and costs.
- Improve relations with your neighbors, legislators and regulators.
- Ensure continual improvement in your operations, boosting efficiency and profitability.
- Empower your employees to work towards common goals, increasing productivity.

For more information regarding Responsible Recycling Practices (R2) or the Recycling Industry Operating Standard (RIOS), please check out ISRI’s website at www.isri.org for more information.



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Meet the Staff

AQA would like to welcome Dennis Gillan as our new Business Development Associate. Dennis comes to AQA with more than 20 years of successful sales experience in the paper, pharmaceutical, and sales industries. Originally born in Brooklyn, NY, Dennis along with his wife and two sons currently reside in Blythewood, SC. In his free time, Dennis enjoys writing and hanging out with his family. With a goal to make AQA a better known entity in the Southeast, Dennis is very excited about his new position and we know he will be a wonderful asset and addition to our company. Welcome aboard Dennis!



TDC Energy Offer

TDC Energy is offering to provide AQA clients located in Ohio a reduction in their commercial electricity costs in an effort to take advantage of electricity deregulation. Operating in a deregulated energy market affords many benefits. TDC Energy gives you the ability to choose who you buy your power from and how it is generated, allowing flexibility in developing an energy strategy that works best for your business. TDC Energy offers services that can help involve multiple suppliers to compete for your energy business, gain protection from rising costs, seamlessly transition from your current supplier to new providers as well as managing contracts, transaction data and complex regulatory requirements. For more information regarding this offer, please contact Cherie Schneider at our AQA Midwest office via email at cschneider@aqausa.com



Upgrading Your QMS to ISO 13485

Article Written by: Ahmet Faruk Taka, AQA

ISO 13485 was issued to ensure that medical device manufacturers were meeting compliance and regulatory standards as set forth by their customers. Certification to ISO 13485 is now a direct requirement for some markets such as Australia and Taiwan, is an indirect requirement for others such as European Union member countries, and can form the basis of GMP compliance in the United States. Although based on ISO 9001, ISO 13485 removes ISO 9001's emphasis on continual improvement and customer satisfaction and instead places emphasis on meeting regulatory and customer requirements, risk management, and maintaining effective processes. All requirements of ISO 13485 are specific to organizations providing medical devices, regardless of the type or size of the organization. Organizations can register to ISO 13485 as a stand alone certification or in conjunction with other standards such as ISO 9001 or AS9100.

Benefits of ISO 13485 registration and things to be considered before upgrading your existing QMS:

- ISO 13485 ensures a consistent and effective approach to business management
- Reduces risk by implementing risk management tools and techniques
- Provides consistency within the medical manufacturing processes
- Yields a better understanding of and compliance to regulatory requirements
- Adds regulatory documents as a part of system documentation
- Requires a device master record like technical file including manufacturing processes
- Provides control of contaminated and potentially contaminated product
- Determines and implements effective communication via advisory notices
- Defines operations for labeling and packaging
- Documents requirements for the installing and verifying the installation
- Documents procedures for the validation of the application of computer software

Achieving ISO 13485 certification is the key of regulatory compliance for medical devices.