INTRASTAGE
ORGANIZING TEST DATA TO IMPROVE YOUR PRODUCT QUALITY

Compliance & Traceability
### Problems Happen...Be Prepared For Them

How to Have a Better Sleep when Mayhem Happens –Using Test Data to improve Compliance & Traceability

When something goes wrong in today's marketplace of mission critical Electronic devices and products, there can be serious repercussions. Consider the case of these 3 stories:

July 2012: India suffered the largest electrical blackout in history, affecting an area encompassing about 670 million people, roughly 10 percent of the world's population.   Three of the country's interconnected northern power grids collapsed for several hours, as blackouts extended almost 2,000 miles, from India's eastern border with Myanmar to its western border with Pakistan. India's government, found itself on the defensive, as they could not definitively explain what had caused the grid failure or why it had happened on consecutive days.

June 2009: The France Airbus that crashed into the Atlantic Ocean was the highest death toll of any aviation accident involving that aircraft type. The reason for the fatal crash was unknown, until finally the black box was located and recovered from the ocean floor in May 2011, nearly two years after the accident. The final report was released that the accident resulted from a succession of events including electrical malfunctions that destabilized the flight path and led to a stall.
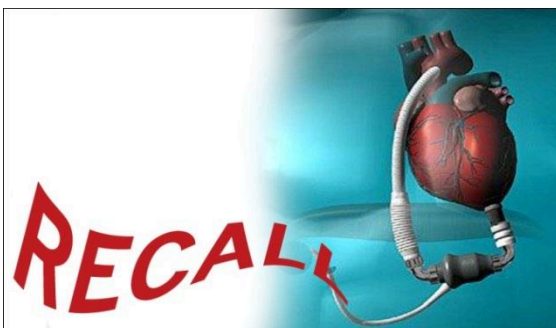
Of all Medical devices, those related to Cardiac devices have the biggest problems when it comes to Recalls.   From a recent report issued by the US GAO (Government Accountability Office) in June 2011, the FDA "could take a more proactive approach to its oversight and dig into their plethora of data available on thousands of recalls, but presently are not effectively reviewing and analyzing the data in a systematic manner. More routine analyses of the data could help the FDA identify trends in the numbers and types of devices being recalled, as well as the underlying causes of device recalls".

All three of the stories are in mission critical industries such as Electrical Power, Aerospace and Medical Devices. Failures of products in these industries can cause serious human harm and disruption. With that responsibility on its shoulders these industries have always focused on compliance and traceability. "Compliance" in the sense of rules that regulate the quality of the product that is delivered to the market and "traceability" that allows failures to be investigated and preventative steps taken for the future.

In this article, we will take a look on how to use product quality Test Data to help tackle some of the trends and challenges around compliance & traceability in these mission critical industries

Compliance Trends

In the last decade from 2000 to 2010, there have been a series of very disruptive shocks that have happened throughout the world. These shocks have impacted about every aspect of the fabric of world society including economic, political, technical and social aspects.

- In 2001 Enron went bankrupt in the largest scandal to date on accounting fraud.
- In 2001 and 2008, there were a series of financial shocks that sent multiple economies around the world into recession.
- In 2001, the terrorist attack on the US caused years of wars in Iraq and Afghanistan
- The internet company Facebook was founded in 2004 and in a short 8 years has over 900 million members, which makes it the 3rd largest country on the planet
- In 2010, Google threatens to leave China over censorship issues. Who would have thought an internet company would be shaping policy in China.

With such a decade of rapid change, the natural inclinations of most governments are to impose regulations to ensure the situation does not get out of control. These regulations can solve some problems but can create costs around compliance to these regulations. With the backdrop of these world events, mission critical industries are now getting caught up in this regulatory and compliance constriction.
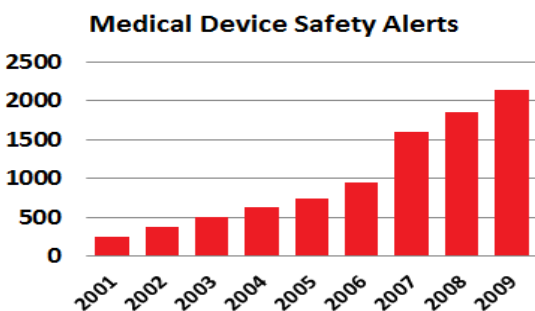
For the medical device industry in the USA, the FDA (Food and Drug Administration) has always been at the forefront of regulating medical devices so that they are designed and manufactured correctly. With the rising number of medical device recalls, this role is getting even stronger.

In the Aerospace industries, the FAA (Federal Aviation Administration) is one of many world aviation regulatory bodies that keep a close eye on devices that are manufactured and designed for aircraft. In this industry compliance is very important, as any catastrophic event can have wide public exposure.

Traceability Trends

Traceability is the capability to find out what happened to a product when it fails in the field or at the customer. Although this is fundamentally important for any electronic product, there is definitely more

emphasis when it is delivered into mission critical industries such as Aerospace, Electrical Power and Medical Devices. These industries have historically been well prepared to show traceability to their customers or to government bodies but at a significantly slow response rate. Today, a response rate of months or weeks which can be typical is no longer acceptable.

This change in expectation on response rate is largely driven by the fact that digitization and the internet have removed most obstacles to achieve full information transparency from supplier to customer. Customers expect that the cost to provide information is fairly low, so they expect when a serious problem occurs that the supplier can quickly and rapidly provide information and fix the problem.

Power has also shifted largely to the customer in these last 15 years due to the emergence of the internet. Before, a serious issue that affected one customer was an isolated event and that issue never got to the larger customer base. Today, the internet is allowing the customer to voice their opinion loudly and widely to the entire world. No longer, can that issue be isolated and controlled. The customer is now in control and is expecting suppliers to fix problems quick.

All these trends are driving pressures on suppliers to have the capability to have full traceability from manufacturing, repair and field Test Data on a failing product.

Making Better Decisions through Data
As issues happen at the customer on specific serialized products whether it be a compliance investigation or traceability on failed parts… most questions first center around the quality of the serialized product and whether there was any indication of a quality issue before it was shipped. In order to investigate this issue, the collection of Test Data is one of the first critical pieces of information that is needed. This Test Data captures the overall quality (Quality is defined here on how well the Test Data matches the desired product's performance, reliability and functionality) of the specific serialized product.

Supplier Components   Software Version   Test Station

Better Decisions

Although it may seem intuitive to capture as much Test Data as possible, this may not necessarily be the right starting approach to make better and quicker decisions around compliance or traceability events. It really starts with capturing the right type of data which refers to the schema and tags that describe the data. Tags like "Software Version", "Calibration parameters", "Operators" etc. all allow more varied ways to slice and dice the data to drill into problem areas. The old saying goes "garbage in…garbage out" holds well here and investing some time and thought on the input data will allow more insights to be derived during these crisis events.
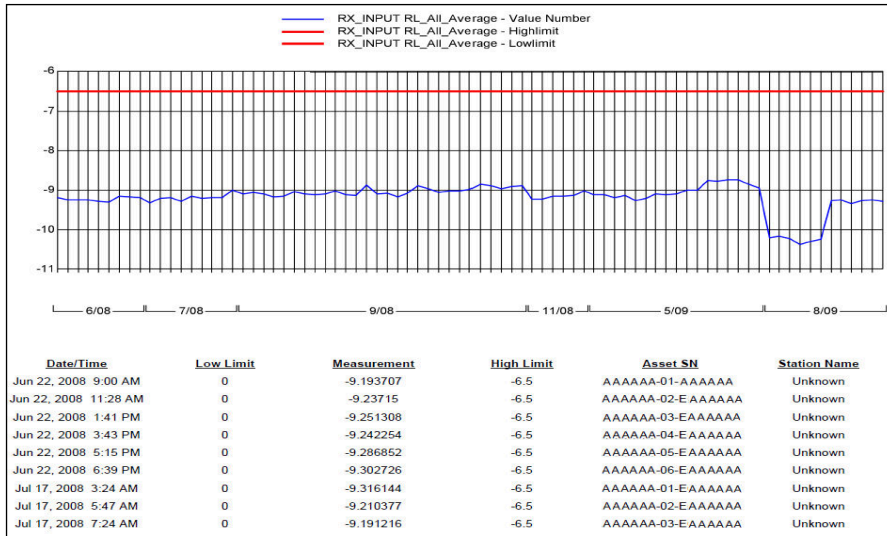
Once the right type of Test Data is captured and with memory storage becoming cheaper storing the gigabytes of Test Data typically generated can now be more cost effectively done. With this trend in increased volume of Test Data it could be a challenge to make quick decisions based on simple reporting as it literally would be like trying to find a "needle in a haystack". Not only would this take a long time using traditional Database query tools, many users who would use the Test Data do not have the technical background to do this. A more efficient way to analyze enormous amounts of raw data is to apply Analytics or Data Visualization techniques to the Test Data.

Analytics is the application of math or algorithms to the data in order to extract trends or potential trouble spots. Such examples of this would be using alerts to indicate sudden yield drops, or using Statistical algorithms to predict deviations.
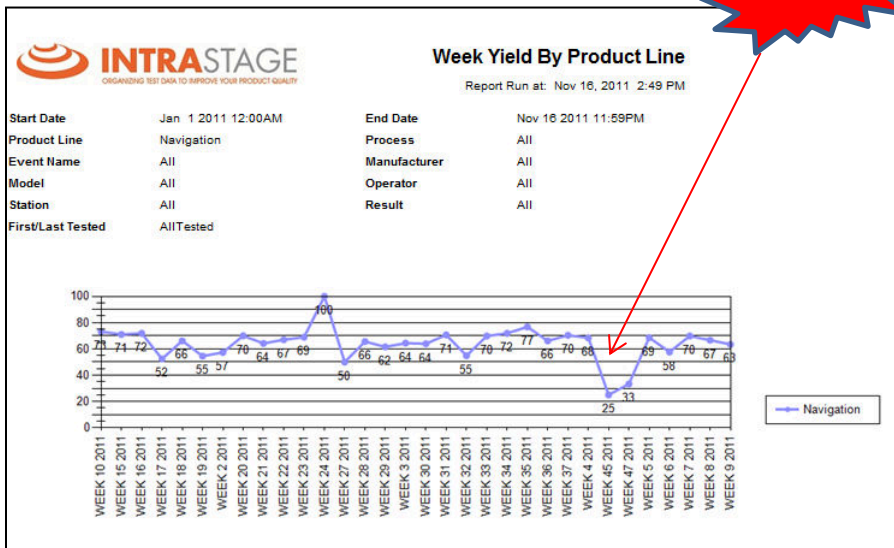
Data Visualization can also be very powerful to sift through and find patterns amongst the massive amounts of Test Data. The human visual system is well suited to parse through massive amounts of data when it is visually presented to look for exceptions and problems.

Date/Time	Low Limit	Measurement	High Limit	Asset SN	Station Name
Jun 22, 2008 9:00 AM	0	-9.193707	-6.5	AAAAAA-01-AAAAAA	Unknown
Jun 22, 2008 11:28 AM	0	-9.23715	-6.5	AAAAAA-02-E AAAAAA	Unknown
Jun 22, 2008 1:41 PM	0	-9.251308	-6.5	AAAAAA-03-E AAAAAA	Unknown
Jun 22, 2008 3:43 PM	0	-9.242254	-6.5	AAAAAA-04-E AAAAAA	Unknown
Jun 22, 2008 5:15 PM	0	-9.286852	-6.5	AAAAAA-05-E AAAAAA	Unknown
Jun 22, 2008 6:39 PM	0	-9.302726	-6.5	AAAAAA-06-E AAAAAA	Unknown
Jul 17, 2008 3:24 AM	0	-9.316144	-6.5	AAAAAA-01-E AAAAAA	Unknown
Jul 17, 2008 5:47 AM	0	-9.210377	-6.5	AAAAAA-02-E AAAAAA	Unknown
Jul 17, 2008 7:24 AM	0	-9.191216	-6.5	AAAAAA-03-E AAAAAA	Unknown

Conclusions

"The number one issue that CEOS face is how to manage the organizations time and energy in the face of growing complexity…the sense that the world is moving faster"
-Chris Zook (Author "Profit from the Core", 2011, Bain & Company)

The finding above in 2011 by Chris Zook comes as no surprise to most people. Product schedules are shrinking, staff levels dictate doing "more with less" and globalization is forcing competition in all areas of the Electronics design and manufacturing business. With this increasing complexity comes the sobering realization that quality issues or failures in the marketplace can only be responded to with accuracy and speed. By making Test Data more accessible and easier to analyze, this will serve as a core part of the response to Compliance & Traceability issues that will inevitably happen.

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