Underwriters Laboratories Inc.

June 2005

AUTOMOTIVE QUALITY SYSTEMS UPDATE

IATF ISSUES NEW FAQ'S AND SANCTIONED INTERPRETATION FOR TS 16949

INSIDE THIS ISSUE:

On May 4th, the IATF released a set of 39 FAQ's and one Sanctioned Interpretation (SI) to the TS 16949 certification scheme. While the SI's are designed to change existing rules, the FAQ's are meant only to explain/clarify existing rules. Regardless, the new releases represent a significant re-definition in several areas of the scheme itself. Those that would have the most impact on our customers are laid out as follows, using the structure of the FAQ/SI documents as cross reference (Note: These documents are publicly available on www.IAOB.org):

- **FAQ 3—What is a subscribing customer?** With this FAQ, the IATF has clarified the definition of subscribing customer to be those customers that require certification/***compliance*** to ISO/TS 16949:2002 of their supply base. While it has always been understood that subscribers included those customers requiring certification (going back to the days of QS), the introduction of those requiring compliance is new to the definition. The good news is that except in cases where an organization has split their scope to include only subscriber products (allowed under TS rule 1.7), this will have no impact on most organizations. For those who have made this split however, the registration may need to be updated on upcoming surveillance assessments in order to incorporate the change as a result of the re-definition. A few key points related to the FAQ are:
  - In some cases, Customer Specific Requirements (CSR's) may allow for certification/compliance to other standards in order to meet supplier QMS requirements. For example, the CSR may allow for certification/compliance to ISO, QS, VDA, EAQF, etc. or TS. In these cases, the customer must be considered as subscribing under the FAQ3 definition for those organizations that seek to meet the requirement by becoming TS certified. We have verified this position with the IAOB.
  - Not every CSR is crystal clear. We recommend that organizations review all CSR's for statements regarding the customers request. If unclear, the organization should seek written clarification directly with the customer's supplier quality or purchasing representative regarding their position on whether they consider themselves to be a TS subscribing customer. There are cases where customers mandate or waive certification/compliance on a site by site basis.

  We recognize this change to the definition may have far reaching impacts (potential addition of remote locations, potential addition of product lines, etc.). The increase in CSR coverage required may also impact the length of the audit, depending on the number of additional CSR's identified. Although the scheme requires us to apply the definition immediately and note non-compliance if the certification is not in compliance with the definition, our staff has been instructed to accept reasonable action plans which may extend across the annual surveillance period, which will hopefully mitigate the impacts.

- **FAQ 15—What is the tolerance on timing of the recertification audit?** The FAQ defines the tolerance as –3 months/+0, which means that the recertification audit cannot be scheduled to begin earlier than 3 years-3 months from the last day of the registration audit, or later than 3 years from the last day of the registration audit. Per the Rules, failure to comply with this requirement would result in cancellation of the certificate. This is different from a normal Surveillance with is allowed a –3/+1 month tolerance. So, for example, if the last day of your Upgrade/Registration audit was May 19, 2005, your triennial reassessment must start before May 19, 2008 in order to avoid a lapse in certification and a complete re-audit. As our scheduling system is predicted on the last day of the audit, this should be no impact to most clients. The point of highlighting it here is to make everyone aware of the requirement and why we won't be able to extend flexibility on recertification scheduling.

- **FAQ 29—Which customers are listed in the certificate appendix?** The FAQ clarifies the requirement of Rule 5.g to include all customers whose CSR's were included in the audit. With this FAQ, we are now able to extend the listing to include non-subscribers, at the discretion of the organization being certified. This will give our customers more options with who can be listed on the certificate. Please note that subscribing customers must still be listed.

The balance of the FAQ's and the SI represent no change to our current implementation of the requirements. Again, full text is available on www.IAOB.org. We hope this helps to clarify the significant impacts of these documents. If you have any questions, contact me at david.parlagreco@us.ul.com.

Tips on Responding to Audit Findings—Root Cause Analysis

If you're reading this newsletter, then you are likely in the automotive industry, and also likely to either be expert in, or have a high degree of exposure to corrective actions systems, tools and methodologies. Disciplined and formal problem solving methods, including root cause analysis, have long been the mantra of the automotive sector. Given this, and based on the theory that to pass a QS or TS registration you already have a compliant corrective action system, this will not be a discussion about how to perform root cause analysis for UL audit findings. Instead, based on feedback from our report review process, we will focus more on how to document these in your response to the UL assessor for their evaluation.

By now, you've likely seen our new TS and QS reports, which require that the explanation of corrective action to UL audit findings be included right in the report itself. This was first presented in the Dec 2004 Newsletter as part of the required changes/improvements that resulted in the Rules 2nd edition roll-out. The associated Rules change was driven by both a need to ensure that the Certification Bodies (CB's) kept the appropriate evidence to support the certificate decision, and to highlight the increased emphasis on ensuring proper analysis and lasting corrective actions were taken on CB audit findings. Feedback from the industry OEM's, along with Oversight Bureau data from witness audits, indicated a level of dissatisfaction with the non-conformity resolution process, with a feeling that CB audit findings had a high likelihood of reoccurrence due to insufficient corrective actions.

In order to address the customer's focus, and ensure an efficient and timely processing of your report, the following tips on responding to the UL AR's are provided:

- If you use a formal method for root cause analysis, like 5 Why for example, include your 5 Why in the response embedded in the report
- Consider inclusion of potential cause considerations that were eliminated as during your analysis to demonstrate an effective methodology
- Repeating the problem is not necessary in the cause area (nor is it the cause)
- In cases where 'oversight' or 'human error' are the likely cause, ensure your analysis includes evaluation of whether the training/qualification process was therefore ineffective
- In cases where the cause was related to a misunderstanding of a TS requirement, include your thoughts related to how the original interpretation was arrived at
- In cases where the cause was related to missing a CSR, include analysis of the system for review of customer specific requirements and potential failure modes within this system
- Special Note—If you need to send examples and separate attachments that support your corrective action to your UL assessor, please send them as separate documents from the report—they cannot be embedded into the report (although you can cut and paste excerpts from MS Word text documents into the report).

Why is this important? First, and most importantly, deep root cause analysis will likely result in a more effective corrective action, increasing the value of the finding and decreasing the likelihood of re-written AR's on subsequent audits, along with demonstrating a robust corrective action system to your customers. Re-written AR's may be considered as majors, based on an indication of an ineffective corrective action system. Also, as mentioned above, thorough Root Cause Analysis will increase the likelihood of first pass acceptance of your AR responses, thereby speeding up the certification decision process. While this has a direct benefit in terms of getting you the certificate (or updated certificate) faster, it also helps to ensure that the TS rules related to timing of AR closure are not violated, thereby jeopardizing the certificate.

Your UL Lead Assessor will be stressing the importance of this activity as part of the audit process, and closing meetings. If you have questions related to this topic, we urge you to discuss it with your assessor, including any specific questions you might have as part of the resolution process.

Quick News on CSR's—New DCX and Ford Clarifications

Effective in May, DCX released it's latest revision of it's TS CSR. The changes were relatively minor and are as follows:

- 4.2.1.3 Special Characteristics—Added a reference to PS-Homologation
- 4.2.1.16 Forever—added specific requirements for notification to DCX Engineering, Supplier Quality and Purchasing, verbally and via the ODD Box form on the Forever system.

While not a formal change, via the audit process we received clarification that the requirements for use of FPDS in Ford 4.22 cannot be currently executed by organizations. UL assessor staff have been notified of this clarification, and that failure to access the system to make updates per 4.22 should not be raised as an AR.

As it appears that Ford may update their CSR later this year (speculation), we will hold off updating the mapping tool on www.UL.com. As always, we will do our best to keep you informed of any changes that occur.

ISO/TS 16949 and the Semiconductor Industry

By Vincent Yann-Ming Wu

Image, as you back out of your driveway, your car notifies you that there's an obstacle behind the vehicle that must be moved. You get out and move the object out of the way, and then you proceed on your way. You're late, and you need some directions. You turn on my on-board GPS system and promptly map the quickest route. You're a little low on gas, but your Hybrid EV gets great mileage – you can make it without stopping. On the way, you hit a huge pothole in the road. Your console informs you that you've had a puncture and you're losing tire pressure. Now you might really be late!

Maybe that's a rough start to the day, but it could have been an awful lot worse without all of the electronic systems that now can be had on today's automobile. On board GPS systems, embedded diagnostic systems, obstacle sensing devices in bumpers, hybrid electric vehicles – today's automotive platforms are loaded with electronic gadgetry designed to perform a myriad of convenience and safety related applications. The expectation of today's consumer has been heightened to the point where many devices that were considered advanced features 10 years ago are now seen as basic requirements on the automotive platform (don't believe it - go look for a car without a CD player). According *Strategy Analytics*, the global automotive electronic market was $122.5 billion USD in 2004, and is forecast to rise 7.5% yearly through 2008 to $163.5 billion. As the automotive industry continues to move from the domain of a mechanically dominated segment towards a higher reliance on more complex and robust electronic systems, more electronics manufacturers will be entering the automotive market segment, and will need robust quality management systems that meet the requirements of the Automotive OEM's.

Market overview for advanced automotive electronics

Regulations and consumer demand continues to spur growth in the automotive electronics market and advanced electronic products (e.g. active tire pressure monitoring systems, hybrid electric vehicles), due to a government pressures for advancements in safety and fuel economy. Today, electrical and electronics system, including software, represent 20 percent of the total cost of a vehicle. A lower-priced vehicle built in 2004 probably has 25 to 30 electronic control systems with 150 to 180 components whereas a higher-priced vehicle might contain 70 or more control modules with more than 400 components.

Carmakers continue to pursue more sophisticated electronics integration. Examples include the system combination such as active safety (e.g., Electronic Stabilization Programs - ESP) and passive safety (e.g., airbag and seatbelt retractors) to create an integrated function (e.g., the ESP system automatically retracts the seatbelt when it senses dangerous driving conditions). Such systems are now being introduced in luxury/high-performing vehicles in the United States, Europe and Japan.

The global automotive semiconductor market, including semiconductor-based sensors, grew by 7.4% in 2003 to $13.9B, and is forecast by the *Strategy Analytics* to reach $24.0B by 2011 due to further deployment of electronic control in emission control, safety and convenience features within passenger vehicles. Clearly the automotive market presents a lucrative opportunity to IC manufacturers.

ISO/TS 16949 in IC industry

Traditionally, semiconductor companies controlled the entire production process, from design to manufacture. Yet many chip makers are now outsourcing/delegating more and more production to others in the industry. Foundry companies, whose sole business is wafer manufacturing, provide an attractive outsourcing option. In addition to foundries, the ranks of increasingly specialized designers, packaging houses and chip testers are starting to grow. IC companies are becoming leaner and more efficient. IC production now resembles a gourmet restaurant kitchen, where numerous chefs line up to add just the right spice to the mix.

Generally speaking, the semiconductor industry is segmented into four main categories:

- **IC Fabless:** Fabless (without Fab) refers to the business methodology of outsourcing the manufacturing of silicon wafers, which hundreds of semiconductor companies have adopted. Fabless companies focus on the design, development and marketing of their products and form alliances with silicon wafer manufacturers, or foundries. (FSA)
- **IC Foundry:** An IC foundry is a company that manufactures IC (Integrated Circuits) for IC design house/Fabless.
- **IC Packaging:** Integrated circuit packaging is the final stage of semiconductor device fabrication in which the bare die or bare boards are placed inside of a protective packaging that provides connectors or pins for connecting to other devices.
- **IC Testing:** IC testing to ensure design compliance and feedback those testing data to IC designer to reduce defects, thereby increasing end product yield.

This structure can present a significant barrier to TS QMS implementation for IC industry. In order to become TS certified, the organization must be a site, meaning it must manufacture something. How then does a Fabless provider become TS certified? The simple answer is that they cannot, at least not by themselves. In one potential solution, they may attempt to partner with a Fab as a Remote Location to the Fab's certification, but even this presents issues in that (a) They are separate organizations, and therefore there are contractual issues in the certification scheme (b) Issues of Intellectual Property (c) Issues related to how the arrangement may limit doing business with other Fabs (d) Issues of risk - will the Certification Body (CB) and the Oversight Body (OB) approve a certificate under this relationship? The same can be said of IC testing houses, which also do not meet the definition of a site (testing is not considered a value-added manufacturing activity).

The conundrum is that the OEM customer requires certification but the Fabless cannot be certified. It has been faced again and again in the industry and as yet there is no good answer, except to try to explain the relationship to the customer and gain acceptance.

While not as harsh, the wafer foundries and packaging houses also face challenges. They are lower in the tier, but may be expected to comply with the OEM Customer Specific Requirements. This in and of itself is not of issue – if there is proper flow-down from the Fabless, but with the Fabless possibly not possessing a clear understanding of the CSR's, this is often lost in the mix.

Even if these barriers can be overcome, the nature of the industry itself presents problems for the TS QMS implementer. IC manufacturers often have far flung networks of design centers and Sales Offices. Under the TS scheme these are considered remote locations, and therefore must be subject to internal and external audits. Without provisions for and acceptance of methods for electronic auditing, that means a visit to the RL, which means cost.

Additionally, the nature of the processes themselves may lend to the complexity of implementation. Part specific approvals and control plans don't always match well with IC batch processing. Many of the devices are not application specific, meaning they are often manufactured to market demand, not to a specific order, while the automotive industry and many of it's core tools are part specific in nature. This exacerbates the approval process in cases where a customer may be asking for PPAP on something that has been in production for many years.

Of course, the simple way to handle this is to make a 'basic' package of documentation that is designed around the process, instead of the part. From this basic package, modifications to address part specific requirements may be made. Use of generic control plans and FMEAs, for example, can help to reduce the paperwork inherent in the system, while retaining it's value. While this doesn't lessen the document control issue if a customer insists on part specific documentation, it can help to reduce the cycle time and increase the efficiency in creating such documentation.

Product and process complexity present additional challenges to the implementer. For example, IC's can be designed with new levels of density and performance while incorporating the functions of an entire system. Die size has been increasing with more and more advanced technology features being integrated into today's system on chip (SoC) designs. These factors become increasingly important for companies to maintain their competitiveness. Wafers may be transported automatically in a 300mm Fab via advanced automation system, such as Front Opening Universal Pod (FOUP) that has a capacity of 25 wafers. A batch movement is executed using Automated Material Handling System (AMHS) for interbay moves, which hand off the FOUPs to Rail Guided Vehicles (RGV) for intrabay moves. And operations of 300mm Fab highly depends on CIM (Computer-aided Integrated Manufacturing) system to increase operating efficiency and to prevent miss operation. Defining the sequence and interaction in such a complex process is no easy task. Additionally, ensuring that TS elemental requirements are addressed is also made more complicated – and this example didn't even include customer specific requirements!

The timeframes involved with design and implementation of such a complex product present a final additional problem – how does one show objective evidence of implementation and meeting all TS/Customer requirements, when a design may take 3-5 years to finalize and manufacture? It is entirely possible that the older work was not done under a compliant system, so there may be cases where a project does not have stem to stern evidence of TS compliance. There's little value in going back to completed projects to create objective evidence to fill the gaps – and we would certainly not advocate that activity. The best solution may be to piece together evidence of compliance of the systems through a number of projects. For example, if your TS design process was initiated last year, it may be possible to show the beginning steps of design on Project 1, the design itself on Project 2 and the Validation on Project 3. A common mistake implementers make is to grandfather their currently on-going projects in and allow them to complete under the old system, rather than cutting in the new process right away to exercise it and gain evidence/data for implementation and improvement. Of course, if one did cut in right away, there may be cases where there may still be gaps to some TS requirements. In this case, it's best to identify them to the CB as early as possible (at the latest during the Stage 1) to determine whether they are such that a path forward can be initiated, or whether the assessment process must be delayed.

To conclude, in 1965 Gordon Moore, then research director at Fairchild Semiconductor, made a prescient observation, later known as Moore's Law. Plotting data on integrated circuits, he observed that each new device contained roughly twice as many transistors as the previous one and was released within 12–24 months of its predecessor. This implied exponential growth of chip capacity at 25–50 percent per year! We are now in the nanotechnology era - requiring new materials, new device structures, and new manufacturing methods, as well as more complex quality management systems. In order to participate in the Automotive sector, organizations need to be proactive in facing the potential problems and barriers to certification in this sector. A big part of this is identifying the situation as early as possible and working with a CB that understands the barriers and can partner with the organization to overcome them. The goal must be to team in order to define a reasonable path forward that ensures a valid certification can be issued, and most importantly, results in a QMS that adds value to the organization and the customer.

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