

24A - Delivering a Compliant and Risk Focused DFR (Design for Reliability) Program for Medical Devices

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Design and development of medical devices has gone through more engineering scrutiny, compliance and rigorous design control process than ever. As a result, reliability requirements flow-down for medical devices has transformed DFR (Design for Reliability) programs into a 'disciplined' and exhaustive process. Defining system and subsystem level DFR requirements, developing test protocols and executing tests as a part of reliability verification process, resolving defects, managing field events through the FRACAS (Field Reporting and Corrective Action System), objectivity through statistical thinking for activities including sample size estimation are some of the elements of DFR process.

This presentation will focus on delivering a high level outline for reliability program with a focus on medical devices. It will highlight the reliability program activities managed through sustained compliance and risk mitigation. Reliability requirements flowdown including test strategies for environmental, shipping and accelerated tests will be discussed. Various commonly known myths regarding reliability programs for medical devices will be addressed.

Presenter:

Nihar Senapati is the Reliability Engineering Leader with GE Healthcare in Lawrence, MA.

He works in hardware and software Reliability areas and holds a MS in Reliability and Quality engineering from University of Arizona, Tucson. He is also a CRE, CSQE, CQE and a Six Sigma Black Belt from ASQ. He has published many papers and consulted in various frontal areas of Reliability, Quality and Six sigma process improvement initiatives. Nihar is a member of ASQ and IEEE Boston Reliability Chapter.

24B - An Improved Approach to Fault Detection / Fault Isolation (FDFI) Verification

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Raytheon Integrated Defense Systems

A system's ability to automatically detect and isolate faults strongly influences its reliability, availability, and maintainability (RAM) performance. Availability can be degraded when an undetectable fault in primary equipment precludes a switchover to its healthy redundant counterpart. Similarly, undetectable faults in standby redundant subsystems provide a false sense of security, since the next fault in the primary subsystem represents a system critical failure. Poor fault isolation has similar effects. The inability of an operator to quickly fault isolate impacts RAM performance by increasing the maintenance timeline (high MTTR) of serial subsystems, thus decreasing system availability. For redundant subsystems, reliability is also affected because of higher vulnerability to subsequent failures while the maintainer services the first failure.

Traditional FDFI verification techniques often involve costly formal demonstrations per government specified test methods (e.g., MIL-STD-471). These methods call for faults to be randomly selected from a sample fault population and injected into the system. Observed FDFI results are then compared against statistical acceptance criteria that include consumer/producer risk factors.

The methods employed to verify FDFI performance can also impact the FDFI performance itself. As a result, verification activities are often performed with a hidden agenda; not just to verify requirement compliance, but also to obtain FDFI maturation through the corrective actions that often result from the verification process.

There are severe limitations to the traditional demonstration approach, including small sample sizes that do not reflect the true fault population, the inability to duplicate the transient/intermittent nature of some faults, and the common practice of performing dry-run testing (and FDFI design improvements) on the entire sample fault list. The latter is often specified and encouraged by the buyer, in order to obtain more FDFI maturation. Despite these well known limitations, procuring authorities of large systems continue to specify traditional MIL-STD-471 methods of FDFI verification.

While requirement verification and FDFI maturation are desirable goals, there is a more effective approach to achieve both. The ideal approach involves a combination of testability modeling and analysis during the development phase, informal fault injection testing during the prototype/production/test phases, and collection of FDFI data from naturally occurring faults during the test and operational phases. The ideal mix depends on the characteristics of the system and capabilities of the organization. This presentation will explore the performance benefits and efficiencies that can be achieved by this timed phased approach, and will provide guidance on selecting the optimal emphasis for each method.

Presenter:

Phillp Bedard has worked in the reliability and quality engineering disciplines for 20 years, including 3 years at Digital Semiconductor, and the balance at Raytheon's Integrated Defense Systems business unit. Phil has earned the ASQ Certified Reliability Engineer certificate, is a member of the IEEE's Boston Reliability Chapter, and has received Raytheon IDS Technical Honors in 2003 and 2006. He is currently enrolled in Raytheon's Systems Engineering Technical Development Program. Phil has been responsible for the RAM analysis and modeling efforts on a variety of high availability radar programs. He has earned a BS in Electrical Engineering from Worcester Polytechnic Institute, and an MS in Engineering Management (w/concentration in Quality/Reliability) from the University of Massachusetts at Amherst.

24C - Power Supplies, COTS Components & Converters Lessons Learned

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One key area of concern in today's electronics applications is overall reliability and performance of power supplies. Variability in quality, reliability, and performance can significantly impact system level reliability attributes, such as Mean Time Between Failure (MTBF) and Mean Time to Repair (MTTR). This also has a great effect on performance and cost attributes, such as Availability, System Complexity (Redundancy), and Total Cost of Ownership (TCO-Maintenance). Almost all components and sub-assemblies used in many of today's power supply designs are comprised of or are classified as standard Commercial Off The Shelf (COTS) grade quality levels.

This presentation will highlight several failure examples of COTS power supply components, modules, and sub-assemblies used in custom, high reliability, military grade applications. The examples cited will include electronic component, power module, sub-assembly, and material and process related failures. Integration and environmental performance issues encountered will also be covered in this presentation. The failure modes, analysis, corrective actions, and key lessons learned for each example will be reviewed in detail. Analysis tools that can be utilized early in the product development stages to assist in COTS risk assessment and mitigation will also be reviewed.

Presenters:

Aaron C. DerMarderosian, Jr. has worked in engineering for 20 years with the last 17 years focused on reliability analysis and assessment, failure analysis investigation, product/program FRACA, design verification test, systems and circuit analysis, accelerated testing, product, process and test engineering. Aaron is a senior member of IEEE, currently serving as the IEEE Boston reliability chapter Chair (2006-2008), previously as vice-chair in 2005. He was recently appointed as Technical Activities system foundation pillar for the Reliability Society (National level), encompassing devices, failure analysis, physics of failure and materials.

Aaron received a technical innovation & inventors award in 1991 for an innovative test method that lead to a patent. He also is a recipient of IDS Engineering technical honors in 2004 and 2007, and author's awards in 2006 and 2007. Aaron has a BS in Electrical Engineering Technology from Northeastern University.

Kenneth P. Rispoli is responsible for failure analysis of semiconductor, electronic, and electro-mechanical devices and assemblies at Raytheon's Material Engineering. He has over 30 years experience in the fields of component evaluation, failure analysis, and application engineering and specification. Recent work includes the assessment and integration of COTS electronics in military systems using Failure Mode and Effects Analysis (FMEA) together with physics of failure methodologies. Ken is an active member of the Electronic Device Failure Analysis Society and IEEE. He is an instructor of Statistical Process Control and Design of Experiments and holds a BS in Electrical Engineering from Merrimack College and an MS in Electrical and Computer Engineering from the University of Massachusetts Amherst.

24D - Planned Availability Maintenance Concepts

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In today's product design environment, it is imperative to consider the whole life of a product. A key aspect of the product life is the maintenance philosophy that will be required during its operation to meet its Availability (Ao) and life cycle cost targets. Today, engineers and end-users have increased their demands, and understand the criticality of conceptualizing the lifelong view of the product.

Maintenance planning to meet Ao and cost requirements includes determining the availability, manpower burden, and the location of and number of spares required to be on-hand in order to retain the product in operating condition. Analysis by systematic trade-offs is accomplished to minimize system interruption and downtime. Planning and executing of the maintenance concept can have a significant impact on the end-user. Life cycle can be impacted by the improper quantity of spares. Too few spares can result in system downtime, while too many spares will require excess storage space and increase costs needlessly.

Today's complex systems demand an accurate and thorough maintenance planning evaluation to meet the aggressive Ao and cost targets expected by our customers. The ability to lower maintenance cost targets as a result of maintenance philosophies is significant to the end-user. The maintenance philosophy includes the performance threshold to initiate the repairs that will allow cost effective manpower burden yet meet system availability within the life cycle cost target.

This presentation discusses the process and details used to analyze Ao maintenance trade-offs to optimize for maintenance interval, life cycle cost, and system operation time for a complex system by use of an example. The impact of the maintenance philosophy and results of the trade-offs is described.

The entire life of the product is considered, from the initial design phase until the product's end of life. The Ao maintenance process plays a key role in the outcome of system downtime and life cycle cost.

Presenters:

Michael S Flanagan is a Reliability and Engineer with Raytheon's Integrated Defense Systems Business in Sudbury, Ma, working on radar systems. He received his BSEE degree from the University of Massachusetts and is currently working at Raytheon Company supporting the RAM activities for IR camera systems.

Pamela Winters is a Reliability and Maintainability Engineer with Raytheon's Integrated Defense Systems Business in Sudbury, Ma, working on state of the art radar systems. She received her BS degree in Mechanical Engineering from the University of Massachusetts and her MS degree in Mechanical Engineering from Rensselaer Polytechnic Institute. Pamela Winters is currently working at Raytheon Company supporting the RAM activities for sea and ground based radar programs.

**24E - Green Initiatives, New European Legislation, Asian Pollution Levels –
How Packaging Can Increase Electronic Reliability in the Face of These Challenges**

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Purpose: Exploring the modern challenges to electronics, from legislation and popular movements to an ever increasingly aggressive environment from the viewpoint of how packaging can be used to help overcome these new challenges.

Military and aerospace equipment, assets, products, and electronic assemblies, are being manufactured, stored and/or deployed or used in increasingly aggressive corrosive atmospheres due to an increase in atmospheric pollution, both in the US and particular in Asia. This is further aggravated by ever increasing complexity of the equipment and assemblies. New European RoHS directive mandates going beyond just the elimination of hexavalent chromium from plated metals, and Lead (Pb) from solder, coupled with a growing Green Movement all are having impacts on how electronics are made, stored and shipped. These issues leave the products significantly more susceptible to corrosion, negatively impacting product performance and reliability.

There will be a review of current legislation in Europe and Asia, moving into the proposed changes and how they may impact packaging, as well as discussing current pollution levels in Asia and the trends associated with a worsening air quality there. The link between these dissimilar topics – legislation in Europe and air quality in Asia is silver and the other metals being used in electronic manufacturing in an attempt to go lead free. These metals are highly susceptible to increasing levels of sulfur in the air. In this context we will review trends in packaging, reviewing a brief history of packaging and how materials have been developed over the years to meet existing challenges.

We will also review current materials and how they fit in with the emerging requirements for packaging. There is a new class of materials that meet the various legislation and green initiatives while providing protection from the increasing levels of atmospheric pollution. These materials will be discussed in depth.

Presenter:

Keith W. Donaldson is President of Engineered Materials, Inc. (EMI) which he co-founded in 1993. Keith's education includes BS degrees in Chemical Engineering and Chemistry from Wayne State University and a Masters Degree in Engineering Management and Industrial Engineering from Northwestern University.

His work background includes being in product development and process engineering at Morton Thiokol and a SPC Process Control Engineer at Ford Motor Company. At 3M he was in Quality Control, Process Engineering and Product Development. Following 3M, he moved to Baxter Healthcare as a Senior R&D Engineer and then a R&D Manager, prior to starting EMI.

The last 23 years he has been active in the fields of electronic, medical, military and anticorrosion packaging, overseeing the manufacturing and R&D operations of products in the US, Europe and Asia.