

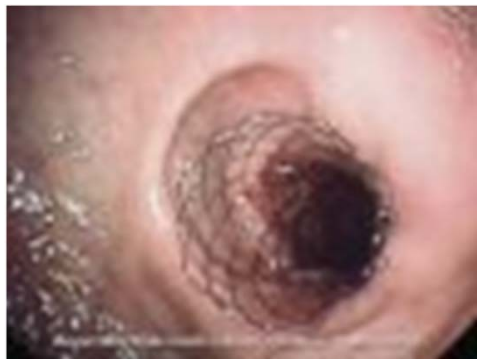
Managing Reliability Expectations & Warranty Costs in Medical Electronics

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ESTC 2010

What is a medical “device”?



More diverse group than medical electronics!



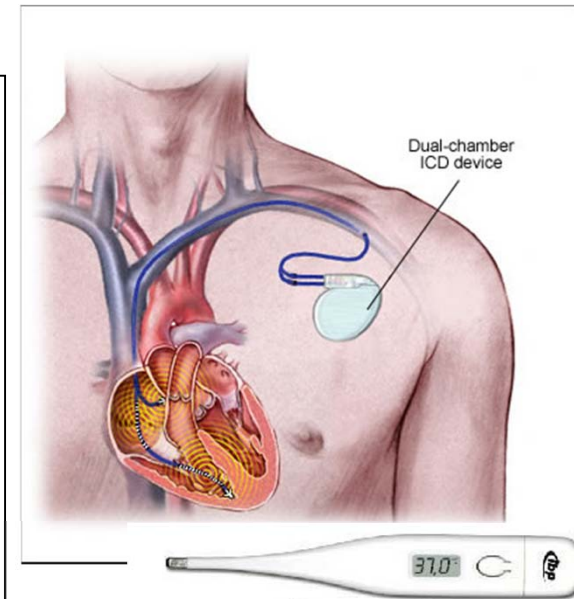
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Medical Electronics – Still very diverse!



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What are 'medical' electronics?

- Is it a realistic category?
 - Some implanted in the body; some outside
 - Some portable; some fixed
 - Some complex; some simple
 - Some control; some monitor; some medicate
- All connected by the perception that one's life may be dependent upon this product
 - Creates a powerful emotional attachment/effect
 - Assuring reliability becomes critical

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Quality & Regulatory Environment for Medical Devices

Medical Device Definition

- Surprisingly, no good, uniform definition of a medical device.
- Increasing overlap in technologies combining medical devices with biologics or drugs.
- Example: *Drug-coated stents*.
 - How the device is regulated depends upon the primary function of the product. Since the stent is performing the primary function of holding a blood vessel open, it is regulated in the US as a medical device. If the primary function was to deliver medication, it would be regulated as a drug. This is an extremely complex area of regulation!



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Medical Device Standards

- Worldwide, the two most commonly accepted medical device standards are:
 - ISO 13485 (EU) – Medical Devices, Quality Management Systems
 - FDA 21 CFR Part 820 (US) – Good Manufacturing Practices for Medical Devices.
 - The ISO standard is the most widely accepted worldwide but is not currently recognized by the US. The two standards are ~ 95% equivalent.
- The Global Harmonization Task Force (GHTF) is currently issuing guidelines for a common worldwide structure for regulating medical devices. <http://www.gh tf.org/>

Global Harmonization Task Force



**Working Towards Harmonization in
Medical Device Regulation**



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Two Basic Regulatory Schemes

- Worldwide, the two basic regulatory schemes for medical devices:
 - US Model:
 - Basic classes of devices identified
 - Specific letter codes to identify products very specifically
 - May hinder innovation since new/novel products require a longer process to have a letter code created for the device in addition to the other regulatory devices
 - Quality management system and registration required
 - Good Management Practices
 - Ongoing compliance mandatory, FDA 21 CFR Part 820
 - Frequency of audits based on classification
 - CAPA feedback (Corrective & Preventive Action)
 - Design controls



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US Requirements Key Points



- In the US, there are three broad classes of medical devices
 - Class I. Example: Toothbrush
 - Class II. Example: Stent, Infusion Pump
 - Class III. Example: Implantable heart pump
- Compliance to the FDA standard is managed by
 - Device submission material
 - FDA audits/inspections
 - Form 483 / warning letters
 - Adverse Event reporting system
 - Typical new approval process takes 1 year or more but is considered relatively efficient by worldwide standards.
- Even the highest risk Class III device manufacturers only get audited by the FDA ~ every 2 years on average.
 - The FDA can issue warning letters or non-compliance letters based on severity of issues found.



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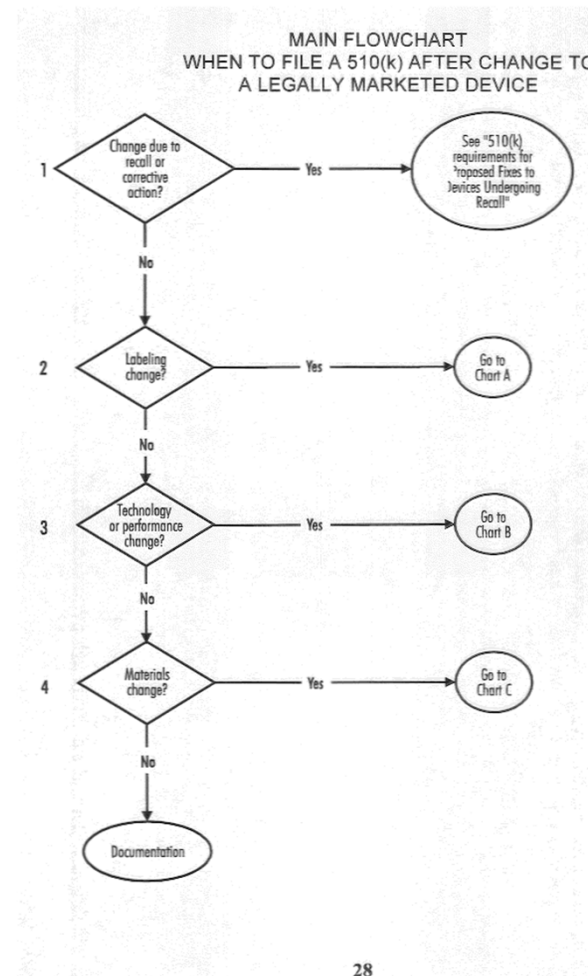
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US Requirements Key Points



- Device changes require FDA notification.
 - FDA flowchart detailing change requirements based on device type & significance of change made.
- Reliability is never explicitly mentioned.



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US Requirements Key Points



- Design requirements are as follows:
 - Design Input, Design Output, Design review, Design verification, Design validation, design transfer, design changes, design history file. No specific testing recommendations or requirements are identified (types of tests, # of units tested, success rates, etc.).
- Quality is handled via the Quality Management System requirements. Again, no hard & fast rules only general guidelines.
 - Statistics / sampling plans / CAPA feedback are required
 - No goals or requirements are set.
 - System seems to encourage setting a low bar on quality since the audits are keyed on attaining goals that were set.
 - Some recognition of risk versus reward in the US, but EU gives greater consideration to this aspect.
 - Example: All medical devices pose an inherent risk to the patient. Even relatively simple ones like catheters can cause death due to blood stream infection. For more complex cases like heart pumps, the device risk may be higher but the patient's risk of non action is also higher. This is given greater consideration in Europe than in the US.

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EU Requirements Key Points

- EU Model
 - CE marking is the ultimate goal
 - De facto expectation to annually certify to ISO 13845
 - Basic classes of devices identified
 - Broad letter codes that are more functional than specific in nature, generic rules not prescribed categories
 - Thought to allow more rapid approval of new/novel devices
 - Risk management required
 - Essential requirements identified
 - Labeling + Language requirements
 - Technical files
 - Design Controls
 - Clinical evaluation
 - Traditionally easier/faster to get certified in Europe than in the US



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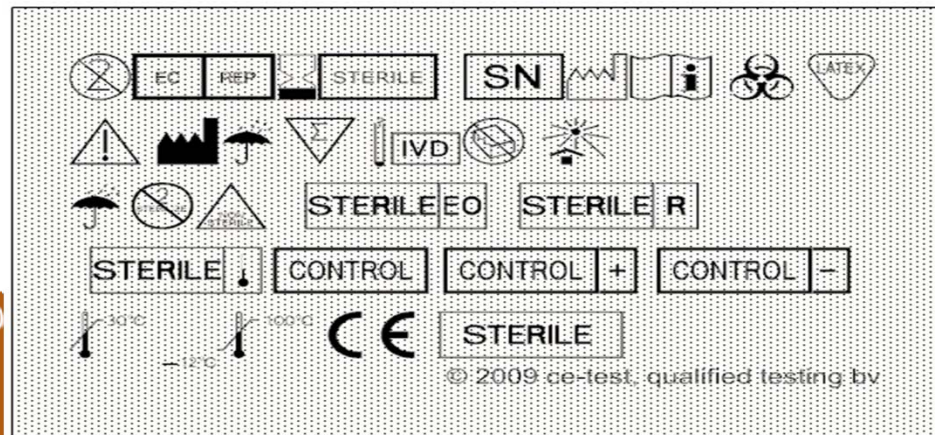
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EU & ISO 13485 – Key Points

- ISO 13485 requires implementation & maintenance of a quality management system.
- End result is a product CE marking followed by 4 digits which identify the notified body.
- Classes I, II, & III with codes MDD (medical), VDD (in vitro), and AIMDD (active implantable, implantable)
- EU makes a distinction between “cosmetic” and “medical” devices. Toothbrushes, wrinkle creams, etc are considered cosmetic and not regulated in the same manner.



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ISO 13485 versus ISO 9001

- ISO 13485 is specific to medical devices. It contains the elements of ISO 9001 plus
 - ❑ Cleanliness requirements
 - ❑ Risk management
 - ❑ Post market surveillance requirements
 - ❑ Implantable requirements

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Reliability Programs and Testing for Medical Devices

Reliability Assurance -- Definition

- Reliability is the measure of a product's ability to
 - ...perform the specified function
 - ...at the customer (independent of environment)
 - ...over the desired lifetime
- Assurance is “freedom from doubt”
 - Confidence in your product's capabilities
- Typical approaches to reliability assurance
 - ‘Gut feel’
 - Empirical predictions (MIL-HDBK-217, TR-332)
 - Industry specifications
 - Test-in reliability
- Must be driven by incorporation and implementation of Best Practices

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Best Practices



- Focus on ‘Best Practices’
 - Corresponding case studies
 - Provides a “buffet” of choices
 - Select those most appropriate for your product and your company
- Similarities among Best Practices
 - Pushes activities earlier in the product life cycle and farther down the supply chain
 - Obtains fundamental information: the when, how, and why
 - Implements feedback loop (i.e., continuous improvement)

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Reliability and Design

- Reliability is all about cost-benefit
 - Every company has a fixed budget & budget limitations!
- Reliability activities are strongly driven by cost
 - Not a revenue generator
 - Increase efficiency in reliability activities: Lower risk at same cost
- Address reliability during the design phase to increase the cost-benefit ratio
 - Caught during design: 1x;
 - Caught during engineering: 10x;
 - Caught during production: 100x

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Reliability Economics

- There are no universal 'Best Practices'
 - Each company must chose the appropriate set of practices that will optimize it's return on investment in reliability activities
- Significant opportunities for Medical Electronics
 - Increasing public perception of issues with medical devices
 - Recalls
 - Adverse events

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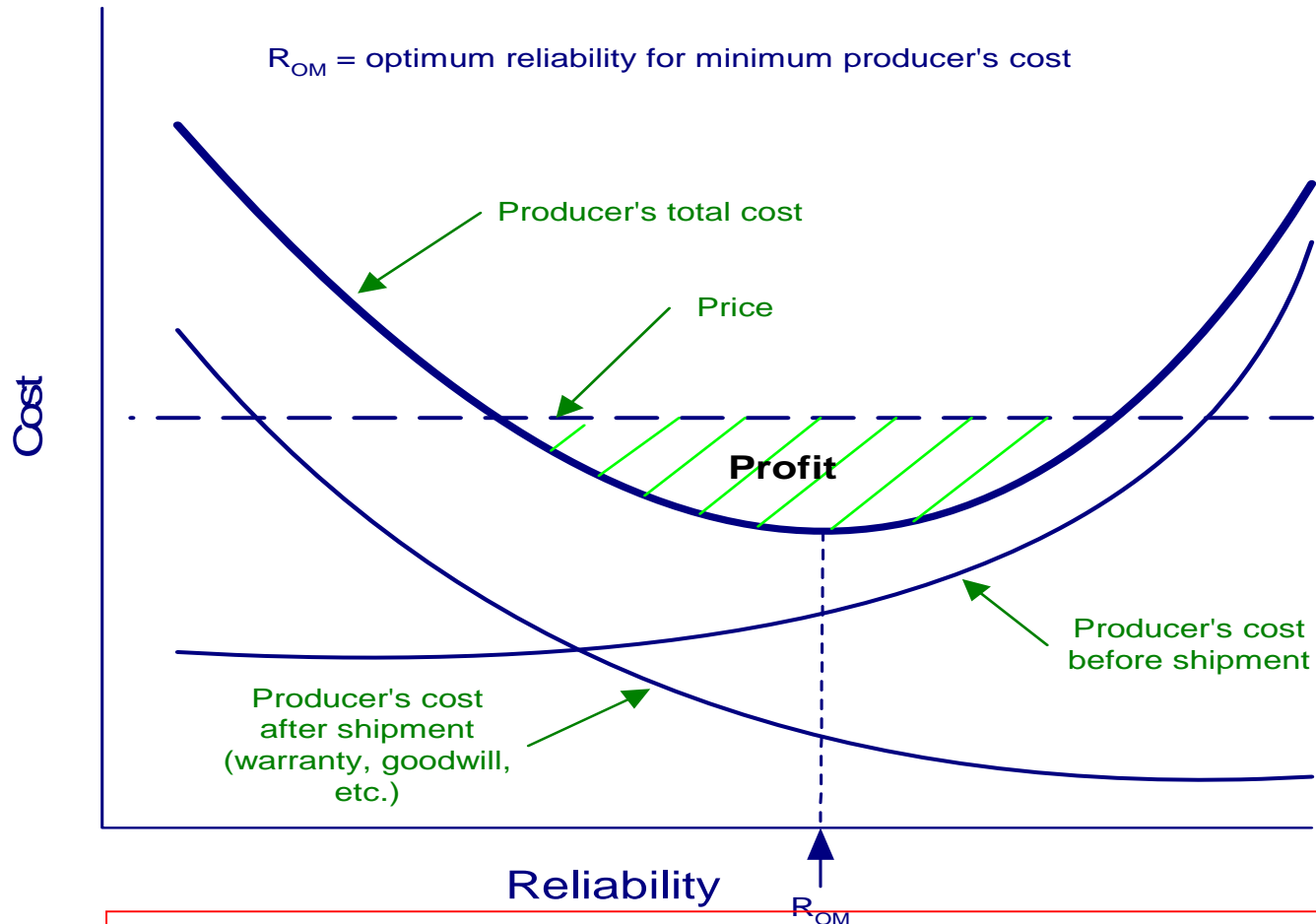
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Reliability Economics, continued

Reliability Impact on Producer's Cost



courtesy of
N. Andersen

Highest Reliability Is Not Necessarily the Most Economical

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Reliability Economics, continued

- Additional drivers
 - ❑ Use environment / design life (wearout an issue?)
 - ❑ Manufacturing volume (leverage over suppliers)
 - ❑ Complexity (what am I missing?)
 - ❑ Profit (how much can I spend?)
 - ❑ Turnaround (how much time do I have?)
 - ❑ Field performance (reduction in rework / warranty costs)

Best Practices Process

- Establish reliability goal
- Quantify the use environment
 - Thermal analysis and assessment
- Circuit and component stress analysis
 - Identify critical components
- Perform failure mode effects analysis (FMEA)
 - Identifies CTQs (critical to quality) and tolerances
 - Allows for development of comprehensive control plans with suppliers (SPC with Cpk's)
- Design for Manufacturability (DfM), Design for Testing (DfT), and Design for Reliability (DfR)
 - Involve contract manufacturers in DfM and DfT
- Step stress tests to define design margins (HALT, highly accelerated life testing)
- Simulation for end-of-life prediction
- Perform the applicable product qualification tests
 - Accelerated life test (ALT) to validate life prediction model
 - Temperature-Humidity-Bias (THB) tests to check for contaminants
- Perform failure analysis on test failures and field returns to initiate feedback loop

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Key Elements of a Product Reliability Plan

- Reliability Requirement & Targets
- Reliability Organization Structure
- Reliability Activities (Reports, Tests, Analyses)
- Schedule
- Supply chain management /oversight
- Listing of relevant standards, specifications, procedures

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General Reliability Management Needs

- Need a corporate policy & visibility
- Reliability integrated into product development
- Reliability specified
 - Define failure
 - Specify environments
 - State Reliability Requirement
- Manage suppliers / contractors for reliability
- Reliability Manual

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General Reliability Management Needs

- Create & work to reliability plan
- Define and Identify external services
 - Test
 - Failure Analysis
- Reliability Training

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Integrated Testing Program

- 5 Key Elements of An Integrated Testing Program
 - Feasibility (or Functional) Testing
 - V&V: Validation & Verification
 - Production Testing
 - Reliability Testing
 - Safety / Regulatory Testing

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Feasibility or Functional Testing

■ Feasibility Testing

- ❑ Functional testing – confirm that design meets basic performance requirements
- ❑ Is it possible?
- ❑ Proof of concept
- ❑ Does it work
- ❑ Failures undesirable

V & V Testing

- V&V: Validation & Verification
 - Conformance to specifications & standards
 - Industry standards like IPC, JEDEC, ISO, FDA, IEC
 - Environmental Testing
 - Failures Undesirable

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Production Testing

- Production Testing
 - Statistical
 - Optimize design & manufacturing
 - Failures undesirable

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Reliability Testing

- Reliability Testing
 - Product will operate without fail during specified life & environment
 - Successful reliability testing requires FAILURE unlike other forms of testing.

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Safety Testing

- Safety / Regulatory
 - May overlap with some others
 - Some fails may be desirable
 - Varies based on industry

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Other Integrated Testing Program Needs

- Documentation & reporting system
- Corrective Action Process
- Test equipment (defined, available)
- Schedule
- Common Approaches across test types
- Parallel test paths across test types

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Sample Size Determinations

- Sample size determination for various types of testing. Some considerations:
 - ❑ How critical is failure? Life threatening?
 - ❑ Cost of hardware
 - ❑ Cost of testing
 - ❑ Availability of hardware
 - ❑ How well critical variables / components can be controlled
- 5-20 is typical range for reliability testing
 - ❑ 4 is considered minimum outside of major systems like satellites, shuttle, etc. or very small quantity builds

How to ID the Best Reliability Tests

- Identifying the appropriate Reliability Test-
Key Points:
 - Must test at increased stresses, not actual expected stresses, to create failures then use this information to improve reliability
 - Only true upper stress limits for reliability testing are test equipment capability & technology limits (solder melt points, etc.)
 - Reduce uncertainty of failures
 - All failure occur on a probability distribution & are impacted by interactions of many factors

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How to ID the Best Reliability Tests

- Identifying the appropriate Reliability Test-
Key Points:
 - Why test at unrealistic stresses?
 - Testing costs money & time so failing faster is better. Improvements possible while still in design cycle
 - Finding fails in house is preferred to finding fails in field/use.
 - Failure distributions & rates are notoriously variable
 - Unknown unknowns – future fails very hard to predict

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How to ID the Best Reliability Tests

- **General Reliability Testing Approach**
 - Perform FMECA (Failure Modes, Effects & Criticality Analysis) / QFD (quality functional deployment) to determine likely service fails
 - Identify stressors
 - Plan to simulate stressors in test
 - Step Stress Testing – Single stressors
 - Fail
 - Fix
 - Increase Stress
 - Repeat
 - Step Stress Testing – Combined stressors
 - Fail
 - Fix
 - Increase Stress
 - Repeat

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How to ID the Best Reliability Tests

- Don't forget Customer Simulation Testing
 - often left out
 - Validate environment and use assumptions,
 - See results from inexperienced and ill users

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Defining Reliability Test Limits

- Key Stressor Factors:
 - Minimums
 - Maximums
 - Rates of Change
 - Differences in operating intensity – at rest versus active - % of time
 - Combined environments
 - Temperature + Moisture for example

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Stress Screening (ESS or ES)

■ General Rules

- ❑ 100% testing
- ❑ Mainly electronic components & assemblies
- ❑ If testing shows few fails, it is either not aggressive enough or product is already highly reliable

■ Testing styles

- ❑ Burn In
- ❑ HASS (Highly Accelerated Stress Screening)
 - Faster, more cost effective
 - HALT POS (Proof of Screen) must be performed

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Highly Accelerated Life Testing (HALT)

- A series of environmental stress tests designed to understand the limitations of the design (discover your margins)
 - Theory 1: The greater the margin between the limits of the design and the operating environment, the lower the probability of failure if defects are introduced during manufacturing
 - Theory 2: Not all field failures are due to wearout (motivation for accelerated life testing). Many failures due to introduction of “energy” into the system from multiple environmental stresses (thermal, vibration, power, humidity, etc.)
- What HALT is not
 - It can not be used to determine long-term reliability
 - It is not an optimum process to identify defective material (defective design, yes)

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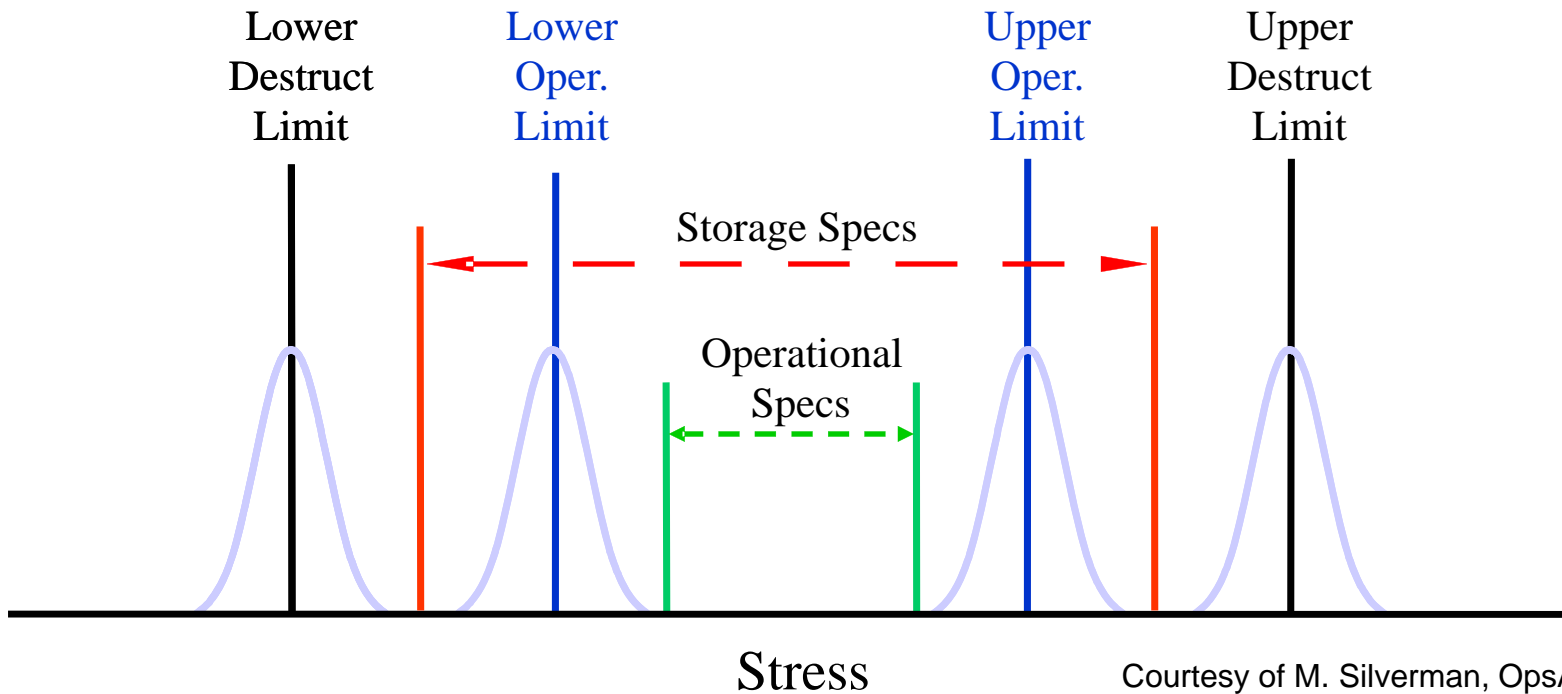
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HALT (cont.)

- Phase One: Step Stress Testing
 - Increases the environmental stress (temperature, vibration, electrical, etc.) until recoverable and non-recoverable failures occur
- Phase Two: Cyclic and Combinatorial Stress Testing
 - Thermal cycling (increasing ramp rates)
 - Thermal cycling + vibration
 - Etc.
- Requires understanding and analysis
 - You can not “pass” HALT
 - Actions based upon failure mechanism and cost of fix

Stress Limits and Margins



- Critical for understanding product limitations
 - If you spec to 50C and the product fails at 52C, how confident are you in the robustness considering nominal variations in component performance?
- Benefits
 - Identifies potential weak points in design before field release

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Step Stress Testing Recommendations

- Perform Voltage Step Stress Test
 - ❑ Both high and low voltage
 - ❑ Test to recoverable and permanent failure
- Perform Temperature Step Stress Test
 - ❑ High and low temperatures with 10 or 15C step
 - ❑ Dwell only long enough to test functionality
 - ❑ Pull max. and min. specified voltage at max. and min. specified temperatures (“paint the corners”)
 - ❑ Perform for both hot and cold temperatures
 - ❑ Test to recoverable and permanent failure
- Perform Vibration Step Stress Test
 - ❑ Starting at 5g and increasing in 5g increments
 - ❑ Finish at 30 or 40g’s

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Case Study -- Cold Step Stress Test

- Mass flow meter
 - Recoverable failure at -30C
- Failure mode
 - Loss of communication
 - No permanent failures observed
- Results of electrical characterization / functional testing
 - Insufficient filtering of electrolytic capacitors (rated at 105C)
- Parametric testing identified drop in capacitance at -35C
 - Freezing of the electrolyte
- Corrective actions that were considered
 - Switch from liquid electrolytic capacitor to tantalum capacitor
 - Switch from 105C rated to 85C rated (reduced lifetime)
 - Increase capacitance from 3.3 uF to 47 uF
 - Extends range as well as improves filtering

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Case Study -- Hot Step Stress Test

- Mass flow meter
 - Permanent failure at 140C
- Failure site
 - Catch diode for a switching power supply
- Failure mechanisms
 - Electrical short (< 1 ohm). Operating junction temp for that part is -65C to 125C.
- Diode was replaced and the unit was functional after exposure at 140C. Temperature was stepped up to 150C, where nonfunctional failure reoccurred

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Case Study – Vibration (1)

- Application of vibration, starting at 5g and increasing in 5g increments
 - First failure noted at 30g
- Failure site identified as connector solder joints
 - Insufficient flow through
 - After touch up unit survived up to 40g
- Incorrect approach to failure analysis
 - Unit was fixed as soon as a problem was detected
 - Root-cause unable to be identified
 - Design for reliability? Design for manufacturing? Processing defect?

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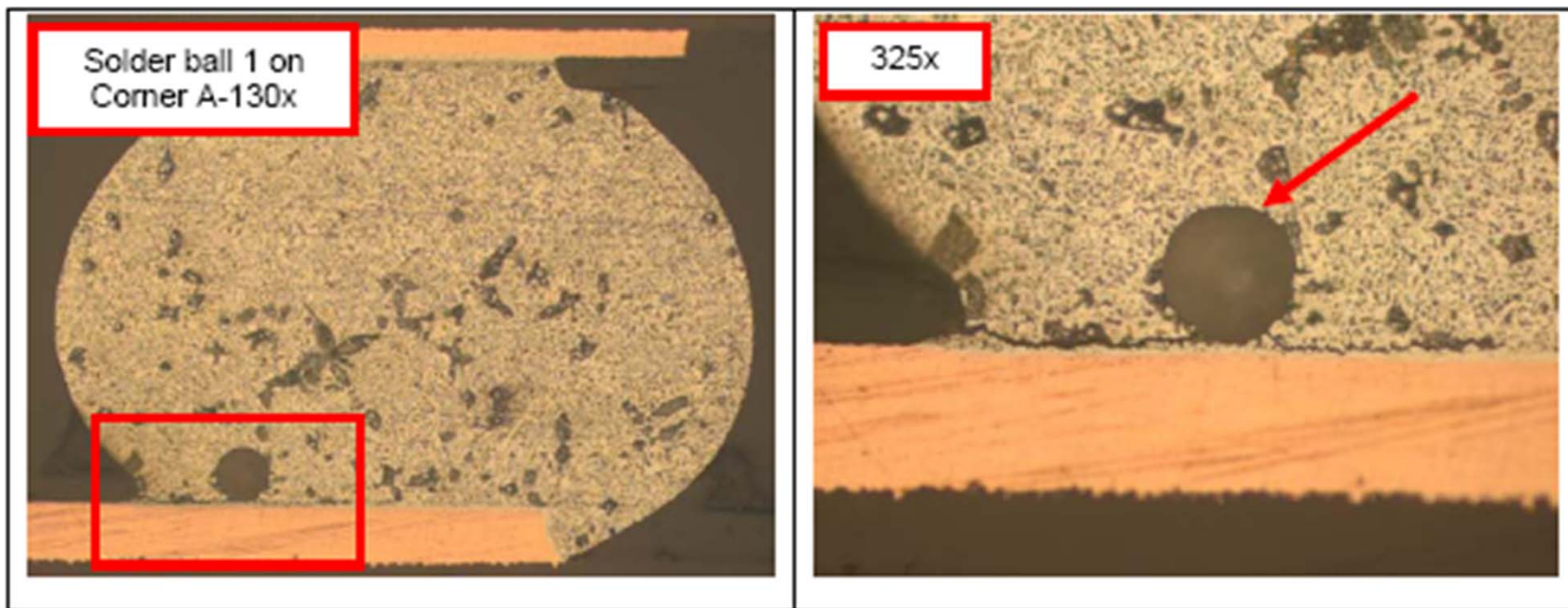
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Case Study – Vibration (2)

- Failure after exposure to vibration
 - Electrical characterization indicated electrical open under area array device
 - Confirmed through cross-sectioning



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Failure Analysis and HALT

- Failure analysis can be a time intensive process
 - Hold up in product release while awaiting results
- The use of failure analysis should be selective and should provide maximum value

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Failure Analysis and HALT (cont.)

- Product
 - When product design or functionality is revolutionary, perform F/A on all failures
 - When product design or functionality is evolutionary, perform F/A selectively
- Temperature Step Stress Test
 - When recoverable failure occurs between the operational and storage specifications
 - Specified to operate between 0 to 70C
 - Specified for storage between -40 to 100C
 - E.g., recoverable failure occurs at 90C
 - When permanent failure occurs within 10C of cold temperature storage specification or within 20C of hot temperature storage specification

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Failure Analysis and HALT (Cyclic Stresses)

- Delineation between when to perform F/A less definitive
- General rule
 - Temperature cycling should not induce any failures, unless using custom designed interconnect
 - Use prior behavior to guide failure analysis in vibration or combined
 - Failure on previous designs is always the electrolytic capacitor at 20g's
- Identification of processing defect can be a design issue!
 - Design for manufacturing

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Failure Analysis & HALT (Case Study)

Cold Step Stress Testing

- LCD Failure at -40C
 - Recoverable
- Within expected material limits
 - LCD operating range is typically -20 to 70C
- Substantial margin below operating specification
 - Product spec'd from 5 to 50C

No F/A necessary

Hot Step Stress Testing

- DC/DC Converter at 110C
 - Non-recoverable
- Failure mode unexpected
 - No recoverable failure observed
- Significant margin above operating specification
 - +60C

Potential need for F/A

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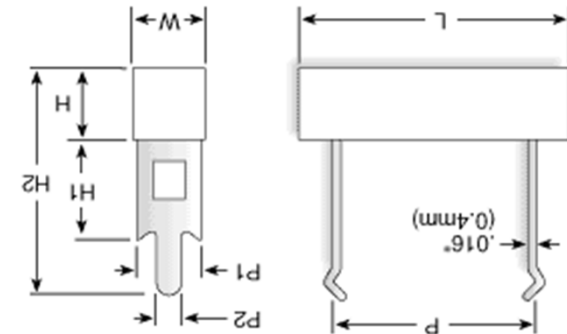
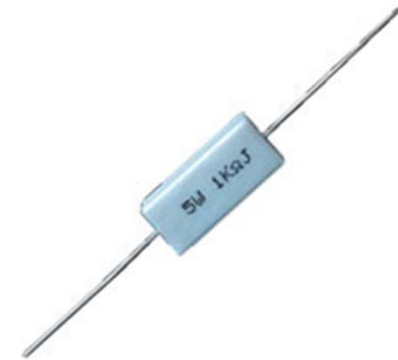
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Failure Analysis & HALT (Vibration Step Stress)

- Multiple failures
 - ❑ At 10 Grms, LED failures
 - ❑ At 15 Grms, Grounding screw loosened
 - ❑ At 40 Grms, Failure of LCD
 - ❑ After test termination, dislodging of ceramic power resistors
- Relevant to use environment?
 - ❑ Vibration only during shipping
- Response
 - ❑ 10 Grms is too low, regardless of environment
 - ❑ Grounding screws should never loosen during vibration testing
 - ❑ LCD failure is at material limits
 - ❑ Minor change in standoffs makes power resistors much more robust



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HALT Case Study (cont.)

Rapid Thermal Cycling

- Sticky relay
 - No repeated occurrences noted
- Intermittent failures are real failures
- “Sticky” relays can be an indication of micro-welding,
 - Due to timing issues or excessive current.
 - Rapid thermal transitions may have aggravated the component or the circuit sufficiently to trigger this event,
- Potential for insufficient margin or robustness

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Conclusion (HALT)

- HALT can be an important step in best practice reliability activities
- Use can be extremely limited with root-cause analysis
- Value-added root-cause analysis requires understanding of failure mechanisms and the stresses that drive them
 - Sufficient knowledge base allows for optimization of resources and rapid feedback

Thank you!
Questions?



Cheryl's Biography



- 20 years in Electronics
 - IBM, Cypress Semiconductor, National Instruments
 - SRAM and PLD Fab (silicon level) Printed Circuit Board Fabrication, Assembly, Test, Failure Analysis, Reliability Testing and Management
 - ISO audit trained, ASQ CRE, Senior ASQ & IEEE Member
- Random facts:
 - Rambling Wreck from Georgia Tech
 - 12 year old son David, Husband Mike, Chocolate lab Buddy
 - Marathoner/Distance Runner – Ran my 1st Boston in 2009 in 3:15!
 - Triathlete – Sprint, Olympic, and Half. Ironman finisher in CDA, Idaho in June '10

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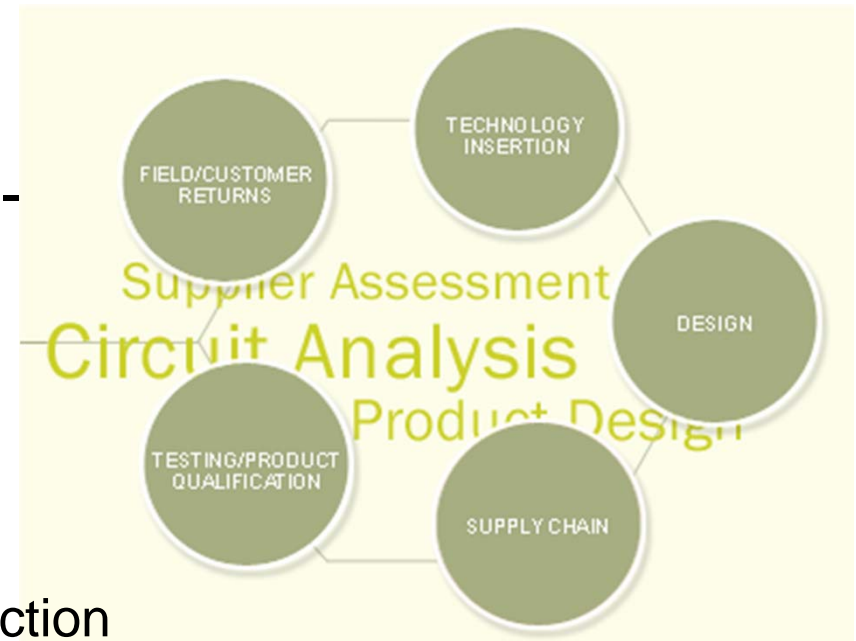
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Who is DfR Solutions?

- We use Physics-of-Failure (PoF) and Best Practices expertise to provide knowledge-based strategic quality and reliability solutions to the electronics industry
 - ❑ Technology Insertion
 - ❑ Design
 - ❑ Manufacturing and Supplier Selection
 - ❑ Product Validation and Accelerated Testing
 - ❑ Root-Cause Failure Analysis & Forensics Engineering
- Unique combination of expert consultants and state-of-the-art laboratory facilities



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*Best Regards,
Dr. Craig Hillman, CEO*

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