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Advancing manufacturing technology
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iNEMI Statement of Work (SOW)
Medical TIG
Medical Reliability for MLCCs (Multi-Layer Ceramic Capacitors) Project

Version 4.0
Date: June 16, 2008
Project Leader: Anthony Primavera (Boston Scientific CRM)
Co-Project Leader: Jerry Peasley (Micro Systems Engineering, Inc.)
TC Coach:

Basic Project Information

Phase II Scope of Work

Determination of accelerated life test methods of long-term leakage and break down failures of MLCCs. This work is a continuation of Phase I. Specific deliverables of Phase II include creation of a test vehicle for use in long term life and accelerated testing of MLCC components.

- Design of Test board
- Fabrication of Test vehicle
- Population of test board with functional MLCCs
- Creation of fixtures and test equipment cables and peripherals at NIST
- Testing of DOE variables from Phase I at NIST Boulder Facility
- Completion of screening experiments at NIST
- Collection of Data and Data Mining resulting failures for trends and insight
- Failure analysis of Test output "Failures as defined in Phase I"
- NIST coordinate Failure Analysis Suppliers
- Phase II Report

Purpose of Project

This group plans to establish of a set of recommendations and specifications that the electronics community would embrace for electronic medical products. Emphasis is on high-reliability applications such as implanted or life critical devices. To this end, medical applications often require rigorous testing, verification, and validation of components before use. There are no widely accepted guidelines for the electronic component and circuit board suppliers to follow for the production of medical grade units. This results in each device manufacturer having its own set of requirements for each supplier. The goal of this effort is, therefore, aimed at providing clarification and identification of guidelines for the industry's supply chain for medical electronics components. The project's Phase I developed use

conditions and supplier risks, which shall be evaluated against available accelerated test methodologies established in Phase II of the Project. While this overall goal of medical guidelines or standards would encompass many different components, the focus of this SOW is for MLCC devices.

Previous Related Work

This project builds on the results of iNEMI's Phase I Medical Grade Component Reliability Specifications Project. The output of Phase I was test and extrapolation methodologies for surface mount multi-layer chip capacitors, serving as an input to non-prescriptive specifications for high-reliability medical grade electronic components.

Specific deliverables included:

1. Test and Extrapolation Methodologies
   - Sampling Population Assessment
   - Range and Conditions of Applicability
   - Test Methodologies and Criteria
2. Medical Grade Guidelines
3. FMEA of MLCC failures
4. Use Conditions for Life-Critical Medical Components
5. Review of existing and related Standards and Test Methods
6. Preliminary Test Results for MLCC devices at NIST
7. Creation for Test ODE matrix for use in Phase II

Participants (as of 6/15/08)

Note – Future Participation is subjected to iNEMI bylaws and regulations.

Company	Lead Contact	Participant and Project Commitment
Boston Scientific	Tony Primavera	PCB Board Design, and Screening Experiment PCBs, Project Management
Celestica	Jeff Kennedy	PCB Assembly Setup, Assembly Materials, Stencil Design and PCB Population
NIST	Grady White	Build Test Fixtures and Conduct Test Phase II Purchased: Agilent Equipment and National Instrument – Boards and Cables Vibration and Humidity Chamber NIST Provided – Computers
Texas Instruments	Carol Primdahl	Statistical Analysis and Data Mining
MED-EL	Peter Lampacher	Electrical Test Review and General Support
Micro Systems Eng.	Jerry Peasley	PCB Board Fabrication, Project Management

Suppliers		Suppliers and Project Commitment
AVX	Karl Eggerding	Components and FA Post Test
Kemet	Philip Lessner	Components and FA Post Test
Vishay	Roger Roberts	Components and FA Post Test

Project Plan
Phase II – Duration

	Phase II **Project Start June 2008** **Project Duration 12 Months**	**1Q June - Aug**	**2Q Sept - Nov**	**3Q Dec - Feb**	**4Q March - June**
	Activity – Owner				
1.	Conduct Per Component Test NIST	X			
2.	PCB Design Boston Scientific, Micro Systems Eng. and Team • Construction • Pad layout • Board size • Connector • Finalize PCB design	X			
3.	PCB Fabrication Celestica, Micro Systems Eng. • Construction • Pad layout • Board size • Connector • Finalize PCB design	X			
4.	Components – Supply - Review AVX, Vishay, Kemet	X			
5.	Assembly Build Celestica • Stencil Design • Stencil Fab • Paste • Printer program • Program P&P • Reflow Oven Profile • Build setup board • Build • Clean • Complete build and send to NIST	X			
6.	Test Equipment – Purchased or made available to Project • Boston Scientific – National Instrument – Boards and Cables • NIST Purchased o Agilent – Equipment and National Instrument – Boards and Cables o Vibration and Humidity Chamber • NIST Provided – Computers Vishay – Precision Resister – Voltage measurement	X			

	Phase II **Project Start June 2008** **Project Duration 12 Months**	**1Q June - Aug**	**2Q Sept - Nov**	**3Q Dec - Feb**	**4Q March - June**
	Activity – Owner				
7.	Test Build NIST • Cables • Test Rack • Tester Setup • Thermal Chamber setup • Vibration chamber setup • Wire Cables to Test board • Build	X	X		
8.	Test NIST		X	X	
9.	Data Mining Texas Instruments			X	X
10.	Failure Analysis Capacitor Vendors				
11.	Webinar – Membership Team				X
12.	Phase II Status Report – Public Forum (Example – APEX 2009) subjected to group approval process.			TBD	TBD
13.	Final Project Report Team				X

Project monitoring plans

- How will you ensure open lines of communication among participants?
  - Bi-weekly conference calls.
  - Meeting minutes provided through email.
  - Follow-up with individuals on an as-needed basis.
  - Workshops and face-to-face meetings as appropriate.
- Planned teleconference schedule.
  - Bi-weekly conference calls.
- Request progress reports as tasks are completed.
- Dates of technical reviews (2 per year) and progress reports and what they will contain.
- Practice risk analysis by anticipating problems and having alternate solutions ready.
  - What happens if??
- Use opportunity analysis to identify new areas or topics that might be addressed in additional projects. This will prevent the scope of the current project from expanding and keep the project focused on original goals.
- Review project requirements with suppliers before the project begins.

Outcome of the project

- Successful completion of this project will include the publication and presentation of the knowledge gap analysis in the public domain.
- Deliverables of this project include the following:
    - Workshop and associated slides for project members summarizing preliminary assessment of the state of knowledge.
    - Final slides and publication of our knowledge assessment.
    - Project results will be shared with the industry in order to drive alignment throughout the supply chain.
    - Knowledge assessment results will be shared through presentations and industry meetings and publication in an archival journal subject to group participant approval process.
    - Updated standards will be shared through publication of the new standards

NOTE: All changes to SOW must be approved by the TC (version control)