



International Electronics Manufacturing Initiative

Lot Homogeneity Review



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November 13, 2006*

- **Introduction**
- **Purpose**
- **Background and Motivation**
- **Scope of Work**
- **Participation**

INPUTS

Use Conditions

- Manufacturing Process & Testing
- Storage (before / after assembly)
- RoHS Compliant Requirements
- Operating (In Use)

USERS SUBGROUP

Existing Standards

- Supplier Plan
- Component Reliability and Assessment

SUPPLIERS SUBGROUP

Supplier Methods, Processes, Risks

- Raw Materials (e.g. for capacitors, Ceramic, Tantalum, Terminations)

COMPONENT RELIABILITY PROJECT TEAM
(Bi Weekly Telcon, Face-to-face 4-6weeks)

OUTPUTS

Accelerated Testing and Extrapolation Methodology

- Sampling/population assessment
- Conditions of Applicability
- Test Methodology and Criteria

LIFETIME PREDICTION & LOT HOMOGENEITY SUBGROUPS

Medical Grade Specifications

STANDARDS BODY

From previous presentation and iNEMI SOW

- **Statistically sound sampling and testing methodologies to minimize, and essentially eliminate, the introduction of defective Multi-Layer Ceramic Chip (MLCC) Capacitors to high reliability electronic medical products such as implanted or life critical devices**
- **OUTPUT**
 - Failure Mode and Effects Analysis requirements
 - Statistical methods to establish quality (initial) performance
 - Statistical methods to establish reliability (time dependent) performance
 - Process capability assessment tools / process control
 - Acceptance criteria (within lot and lot-to-lot)
- **ACCOMPLISHMENTS**
 - Industry First collaboration within medical electronics supply / value chain
 - Significant participation from international supply base and end user groups
 - Substantial progress toward targeted completion date (Feb 2008)
- **OPPORTUNITIES**
 - Expand participation profile – Suppliers, Medical manufacturers, Institutions and Universities
 - Leveraged focus on portable and large equipment needs

- **Quality**
 - Time zero failures, related to manufacturing processes
 - Process control focus
 - Acceptance sampling
- **Reliability**
 - **Definition:** The ability of a product to perform as intended (i.e. without failures and within performance limits) for a specified time, under the life-cycle application conditions.
 - Time dependent failures, related to design, material, chemical, etc...
 - Accelerated testing, qualification testing, HALT, HASS, ORT
- **Maverick Lots**
 - Anomalous manufacturing lots that show behavior different than the expected distribution.
 - Test, process control, acceptance sampling

- **Identify and understand problematic areas and issues**
 - Bottom-up approach
 - Top-down approach
- **Implement necessary programs and changes**
 - Process capability
 - Process control
 - Acceptance criteria
 - Within lot and between lot homogeneity
 - Define sampling plans
 - Supplier perspective
 - OEM perspective
- **Establish culture of continuous improvement**

- **Participation is required from:**
 - OEMs
 - Suppliers
 - NIST
 - FDA?

- *Who can help?*

- *Questions? Ideas? Input?*