

iNEMI Statement of Work (SOW) Medical TIG iNEMI Medical Grade Components Reliability Specifications Project

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Purpose:

This group plans to establish 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 their 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.

Background and Motivation:

Drivers such as high quality and reliability, shorter development cycles, simplified supply chain, extended product life cycles and increased complexity of active electronic implants have resulted in a need for non-prescriptive guidelines and specifications for assessing the reliability of electronics components used in implantable devices. The goal of the Medical Grade Components Reliability Specifications project is to leverage industry knowledge to create a minimum set of requirements for electronics components for application in implanted or **life critical devices**. This will allow component suppliers' access to the entire industry by providing commonly accepted testing, extrapolation analysis, materials, and processes. Medical device manufacturers will achieve proven quality, reliability, and consistency from these components.

Scope of Work:

The key outputs of the Medical Grade Components Reliability Specifications Project are test and extrapolation methodologies leading to non-prescriptive specifications for high reliability medical grade components. In general, failure mechanisms and failure modes are dependent on either inherent (intrinsic) or anomalous (extrinsic) defects produced in the manufacture of the components. Furthermore, the rate of failures is determined by the use conditions. For many electronics components, there is substantial industry knowledge in the form of standards and publications, which can significantly improve the efficiency of the project resource utilization. In the following sections, further details of the use conditions, existing standards, and supplier risks are provided.

Use Conditions: An implantable life-critical device consists of one or more of electronics modules, batteries, charge capacitors, and other electro-mechanical components. The components used in the devices may be subject to a wide range of electrical, environmental, temperature, and mechanical stresses during storage, manufacturing assembly, manufacturing test, device transit, and operation. The conditions during these various stages of manufacture can influence the reliability of the component in service. A comprehensive list of these conditions shall be documented.

Current implantable life-critical devices are "out-of-scope" of the RoHS compliance requirements. However, given the general direction of the electronics industry to be RoHS compliant by July 2006, and the consequent risk of supply discontinuity of conventional materials, implications of using RoHS compliant materials and processes in implantable life-critical devices shall be considered.

In current implantable life-critical devices, these components are hermetically sealed in a biocompatible housing and do not make physical contact with body tissue or fluids. However, in anticipation of future

biometric and implantable patient monitoring devices, which may require components proximity to the body tissue, biocompatibility requirements shall be incorporated in the use conditions. The biocompatibility requirements are specified for reference for future projects. Biocompatibility metrics will not be required for components that are hermetically sealed in a biocompatible housing.

In summary, the use conditions shall include the time dependence of stresses (thermal, mechanical, environmental, and electrical and biocompatibility) and RoHS compliance during the following conditions:

- Manufacturing Process
- Manufacturing Testing
- Storage (before and after assembly) and Transport
- Operating (in use)

Existing Standards: Numerous industry standards exist for common commodities for component designs (JEDEC, IPC, EIA), use conditions (BS-EN 45502), stress testing (MIL, JEDEC), reliability assessment (IEEE-1413), measurement techniques and sampling plans. The project shall compile these standards to evaluate range of applicability and gaps that require further effort.

Component manufacturing / supplier risks: The defects introduced during the manufacture of the components influence the expected reliability of components. The significance of these defects and the associated risks in the use conditions are determined by the processes, test and inspection methods, and materials. The probability of occurrence, severity, and detection of common component manufacturing defects shall be documented in a FMEA or equivalent format.

Outputs: The output of the project shall be test and extrapolation methodologies for specific commodity categories, which shall serve as an input to non-prescriptive specifications for high reliability medical grade electronic components. For each commodity type (or category), the use conditions and supplier risks shall be evaluated against available accelerated test methodology standards. Existing standards/approaches shall be used where applicable. New guidelines will be proposed where gaps exist. Biocompatibility metrics will not be required for components that are hermetically sealed in a biocompatible housing.

Specific deliverables include:

1. Test and Extrapolation Methodologies
 - Sampling Population Assessment
 - Range and Conditions of Applicability
 - Test Methodologies and Criteria
2. Medical Grade Guidelines

The focus commodity categories are (a) discrettes (e.g. surface mount multi-layer chip capacitors, surface mount tantalum capacitors, surface mount resistors and surface mount inductors); (b) array packages (CSP, BGA); (c) substrates and interconnects; and (d) hybrids. The application to surface mount multi-layer chip capacitors will be the first area of focus. Future updates will detail plans for other commodity categories. Portable and non-portable applications will be considered as the next priority.

Schedule:

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
DISCRETES (MLCC)								
Form Team, Assign tasks	■							
Define Use Conditions		■	■	■				
Define Existing Standards		■	■	■	■			
Define Supplier Risks		■	■	■	■			
Define Accl. Testing/Extr Method.		■	■	■	■	■		
Team Review						■		
Make Revisions per Team Review					■	■		
Assemble into a draft document					■	■		
Review Draft						■	■	
Approve Daft						■	■	
SUBSTRATES								
AREA ARRAY								
HYBRIDS								
				TENTATIVE (18months)				
				TENTATIVE (18months)				
				TENTATIVE (18months)				

Resources Required from Participants:

iNEMI member companies will encourage the participation of individuals from different disciplines and divisions within their organization to contribute on the range of tasks outlined in the project plan. The group should contain members from or working closely with representatives of:

- OEMs
- Component and board manufacturers
- Assembly EMS providers