

Draft

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iNEMI Statement of Work (SOW) Medical TIG iNEMI Medical Substrates Project

Instructions for use:

1. Save this file as "Project Name Statement of Work Draft 1"
2. All bold headings should be left as they are. These will form the structure of the document.
3. The Basic Project Information section should cover all the bulleted items, but only *briefly*. The first draft will consist of only this basic information. Later drafts will include detailed information in the Project Plan section.
4. The bullets beneath each heading are suggestions of what should be included in that section. All bullets may not apply to all projects. If none of the bullets apply, then substitute what you think is necessary or simply state "not applicable". Do not delete the heading even if it is not used.
5. For the first draft, the Project Plan section will usually not be filled in. Just state "Project Plan is being developed". Leave all the headings in place so that it will be easy to fill in the Project Plan in subsequent drafts. When you are ready to include the Project Plan, provide *all* available details for each topic.
6. In the Project Plan section, if there are more than two phases, add additional section via cut and paste. If the project consists of just one phase, delete the entire phase 2 section.
7. When you are finished, delete these instructions.

Version 2.0
July 17, 2007

Project Leader: Thomas Jacob, Dyconex
Co-Project Leader:
TC Coach:

Basic Project Information

Scope of Work

- Describe what work will be done
The project team is proposing to investigate the characteristics of substrates used for implantable medical electronics. The initial element of this project will be the identification and analysis of the specifications for substrates used in implantable medical electronics. The project will further investigate the effects of feature size material effect, harsh cleaning, bend radius cracking and mechanical fatigue and low strain-stress high cycle fatigue.
- State the major goals of the project at the end of project deliverables
 - Technical reports outlining the substrate technologies for implantable medical electronics
 - Phase 1
 - Identify gaps in the specifications needing further investigation
 - Phase 2:

- Develop a test vehicle(s) for this and future phases
 - Investigate feature size material effects
- Phase 3
 - Investigate harsh cleaning and rework effects
- Phase 4
 - Investigate effects of bend radius, cracking, and mechanical fatigue
- Phase 5
 - Investigate effects of low strain-stress high cycle on mechanical integrity of the substrates
- Provide an approximate timeframe for major phases of the project and for completion
 - Phase 1 – 7 months (see details below)
 - Phase 2 – 6 months (3 month test vehicle design and 3 month testing)
 - Phase 3,4, 5 – 3 months each (assuming all test vehicle are prepped for testing)

1. Define Characteristics:

Phase 1: Data Mining (duration 7 months)

- Define medical electronics covered for this project
 - Completely encased
 - No exposure to bodily fluids
 - Human implantable devices
- Collect and compile materials, design rules, and board architecture for Implantable Medical Electronics (2 months)
 - Define data collection agent (NIST??, ...)
- Collect and identify the relevant specifications (1 month)
 - Board acceptance criteria (OEM, EMS)
 - Assembly (OEM, EMS)
 - Raw material (Board Mfr, OEM, EMS)
 - Quality control (Board Mfr., OEM, EMS)
 - Use Conditions (Board Mfr., OEM, EMS)
 - Test procedures (Board Mfr., OEM, EMS)
- Define interdependencies for each specification area and the impact on the materials, design rules, and board architecture (1 month)
- Identify gaps in the specifications that need further investigation/evaluation as part of Phase 2 – 5 (1 months)
- Provide Project Team with technical report identifying materials, design rules, board architectures and relevant specifications with a summary for the general iNEMI members (6 weeks)
- Define project tasks for Phase 2 (6 weeks) – requires approval from iNEMI Technical Committee

Phase 2: Feature Size Material Effects – (CAF, low power, high voltage, and miniaturization)

- Review and examples of known failure modes for each
- Via and conductor pattern integrity
- Solder Mask Adhesion
- Cleanliness
- Report on Phase 2 results
- Define project tasks for next phase – requires approval from iNEMI Technical Committee

Phase 3: Harsh Cleaning and Rework

- Review and examples of known failure modes for each
- Via Quality / Integrity
- Report on Phase 3 results
- Define project tasks for next phase – requires approval from iNEMI Technical Committee

Phase 4: Bend Radius / Cracking / Mechanical Fatigue (Handling, folding, etc.)

- Review and examples of known failure modes for each
- Report on Phase 4 results
- Define project tasks for next phase – requires approval from iNEMI Technical Committee

Phase 5: Low strain-stress high cycle fatigue

- Review and examples of known failure modes for each
- Pressure Exposure
- Shock and Vibration
- Report on Phase 5 results

Purpose of Project

- Explain how the project aligns to the roadmap and what gaps will be filled
 - The project will investigate specific characteristics of substrates used for implantable medical electronics. The group will investigate the effects of feature size material effect, harsh cleaning, bend radius cracking and mechanical fatigue and Low strain-stress high cycle fatigue.
- Will the project provide a complete solution or be part of a complex solution?
 - This project is expected to provide elements that assist in better defining specifications for the substrate materials, board architecture, and design rules used in human implantable medical devices.
- List anticipated benefits to participants, to the iNEMI membership in general, and the industry
 -

Previous Related Work

- Review any related research or development done within the industry
 - None known
- Summarize, briefly, directly related academic research, if any
 - None known

Participants

- List all participants and their managers. Strive to include representatives of all facets of the industry, including customers, suppliers, and manufacturers.

Prospective Participants

- Alan Allan Intel
 - Thomas Jacob Dyconex
 - Jana Carraway MSEI
 - Dale Lee Guidant
 - Anthony Primavera Guidant
 - C.K. Barlingay Microchip
 - Robert Gosliak HEI, Inc
 - Jeff Brown Medtronic
 - TBD
- State role and expected contributions of each project team member
 - TBD
 - List any known background IP for each participant
 - TBD

Project Plan

Schedule with Milestones

- Project plan with identified tasks, intermediate check points, and end dates
- A detailed timeline, including each project activity and each scheduled project review. Use the following format:

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Phase 1								
Task 1	Red							
Task 2	Yellow	Yellow	Yellow					
...	Yellow	Yellow	Yellow					
...	Yellow	Yellow	Yellow					
...	Yellow	Yellow	Yellow					
...					Red			
...					Green			
...					Green	Green		
...						Blue		
Task n						Blue	Blue	
Phase 2				TENTATIVE (18months)				
...				TENTATIVE (18months)				
...				TENTATIVE (18months)				

Phase 1 – Detailed Information

- **Task 1 – Task n (include the following information for each task in a separate bullet list)**
 - Resources
 - A detailed list the resources needed and expenditures expected for the project, including human resources, money, and equipment
 - List of committed resources from participating companies
 - State source of funding for any components, assembly, design, and testing needs. Alternatives include participant donation, iNEMI direct funding, and supplier donation.
 - Materials and Processes
 - Identify the materials to be used. Standard materials should be used whenever possible. Use of standard materials reduces costs, improves yields, and assures the widest applicability of results within the industry. Justification should be provided if non-standard materials are to be used.
 - Describe any processes to be used, including applicable standards and specifications. Use of standard processes reduces costs, improves yields, and assures the widest applicability of results within the industry. Use of any non-standard processes must be justified.
 - Any specific suppliers or technologies required and reasons for the requirement
 - In cases where custom components are necessary, state which project participant is responsible for assuming this cost
 - Testing Procedures
 - State anticipated number of parts to be tested. Use discrimination in choosing samples for failure analysis to maximize ROI.
 - Use IPC 9701 0-100C as baseline ATC unless justification can be given for alternate test parameters
 - For test vehicle design and fabrication, it is recommended that reference components that have been ATC tested on previous projects be used to provide a baseline and facilitate comparison of results between projects.
 - Explain design protocol. Use standard design practices and commonly used software to reduce costs and widen applicability of results.
 - At what stages testing will be done and time needed

Phase 2 – Detailed Information

- **Task 1 – Task n (include the following information for each task in a separate bullet list)**
 - Resources
 - A detailed list the resources needed and expenditures expected for the project, including human resources, money, and equipment
 - List of committed resources from participating companies
 - State source of funding for any components, assembly, design, and testing needs. Alternatives include participant donation, iNEMI direct funding, and supplier donation.
 - Materials and Processes
 - Identify the materials to be used. Standard materials should be used whenever possible. Use of standard materials reduces costs, improves yields, and assures the widest applicability of results within the industry. Justification should be provided if non-standard materials are to be used.
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Project monitoring plans

- How will you ensure open lines of communication among participants?
- Planned teleconference schedule
- 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
- 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

- Define project success, including what gaps will be closed
- List all deliverables

- State which project results will be shared, with whom, and by what means

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