1.0 PURPOSE

To ensure that the design and development of products including design changes, is controlled through planning, implementation, review, verification and validation.

2.0 SCOPE

All products developed by EMCO ELECTRONICS for manufacturing

3.0 REFERENCES

DD00 - 401 Format  "Design Plan"
DD00 - 402 Format  "Design Change Record"
DD00 - 403 Format  "Design Review Redord"
DD00 - 404 Format  "Summary of Design Measures"
DD00 - 501 Format  "Check list for Design Input Adequacy"
DD00 - 502 Format  "List of Design Outputs"
DC00 - 403 Format  "Masterlist of Documents (Internal)"
ITXX - 402 Format  "Test Reports"
PD00 - 201 Procedure  "Procedure for Production"
MK00 - 201 Procedure  "Procedure for Contract Review"
DC00 - 201 Procedure  "Procedure for Document and Data Control"

4.0 ANNEXURES :
Annexure A - Process Maps & Flow-Charts
Annexure B - Records Table
Annexure A - PROCESS MAPS & FLOW-CHARTS

<table>
<thead>
<tr>
<th>Process Owner</th>
<th>Process Controls</th>
<th>Process Performance Targets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head Design</td>
<td>---</td>
<td>• Completion as per plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Actual cost not exceeding 5% of planned cost</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Inputs</th>
<th>Process Name</th>
<th>Process Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Customer requirement</td>
<td>Design and Development</td>
<td>• Design Plan</td>
</tr>
<tr>
<td>Customer Feedback</td>
<td></td>
<td>• Design Verification Records</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Design Validation Records</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Design Review Records</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Design Change Records</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Verification</th>
<th>Process Resources (Means):</th>
<th>Process Measures (Metrics):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through Auditing and Process</td>
<td>Availability of softwares</td>
<td>• % Delay in implementation.</td>
</tr>
<tr>
<td>Performance Measures</td>
<td></td>
<td>(DD00-404)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• % Actual cost : Planned cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(DD00-404)</td>
</tr>
</tbody>
</table>
Design and Development Process:

New product / Non-standard product / Design change requirement from Marketing through Design Input Specification

- Design change
- Design input specification
- Non-standard
- New product

Review of Design Input specification for adequacy as per Check list for Design input Adequacy

- Information adequate?
  - Yes
  - No
    - Obtain necessary information through marketing

A1.1
Preparation of Design & Development Plan, indicating the following:
- Design & development stages
- Review, verification & validation as appropriate to each stage
- Defined responsibilities
- Review & updation of plan

A1.3
Preparation of appropriate Design & Development Outputs as per list of Design outputs

A1.4

A

A1.2

No
Verification of Design Outputs at the stages defined in the Design & Development plan for confirming that the same have met the Design Input specification. Results of Design Verification are Recorded.

Review of Design & Development Outputs with concerned functions, (namely marketing, purchase, production, QA, service as applicable), at the stages defined in the Design & development plan, for confirming that there are no concerns, issues relating to:
- 'marketability'
- 'procurability'
- 'manufacturability'
- 'testability'
- 'servicability'

Any comments / changes required?

Correction of the Design outputs as per the comments / changes required by the concerned functions
Customer approval required?

Yes

Forwarding of required drawings / documents to marketing for obtaining customer's approval

No

Manufacturing of prototype

Des. Hd.

A2.2

Forwarding of required drawings / documents to marketing for obtaining customer's approval

Des. Hd.

A1.9

Drawings / Documents approved?

Yes

Modification of drawings / documents as per customer's comments and re-submission to customer for approval

Des. Hd.

A2.1

No

Functional Verification Check List

A2.3

Testing of prototype

Des. Hd.

Yes

Test Report (Product)

ITxx-402

No

Necessary changes / modifications carried out

A2.4

Prototype send to customer where agreed for field test and feedback

Des. Hd.

A2.5

Updating of Master-list for the final drawings / documents

Des. Hd.

Master List of Documents (Internal)

DC00-403

Functional Verification OK

No

Yes

C
A2.6
Manufacturing of Pilot Batch where necessary, as per manufacturing process

A2.7
Final Inspection and testing of Pilot Batch as per procedure for production, as validation of design

Test Results OK?

Yes

A2.9
Release of drawings / Documents to production / QA / Stores as per procedure for Document and Data Control

A2.8
Necessary modifications / changes carried out and drawings updated for the same

No

A3.0
Design Changes are implemented as per requirement

- Design Changes are verified, reviewed & validated as appropriate including effect of changes on existing design
- Results are recorded in Design Change Record

A3.1
Design Change Specification

A3.2
Related Documents are revised & Design Change Record is updated

A3.3
Procedure for Design Changes are verified, reviewed & validated as appropriate including effect of changes on existing design

A3.4
Results are recorded in Design Change Record

A3.5
Related Documents are revised & Design Change Record is updated

A3.6
Release of drawings / Documents to production / QA / Stores as per procedure for Document and Data Control

A3.7
Final Inspection and testing of Pilot Batch as per procedure for production, as validation of design

A3.8
Necessary modifications / changes carried out and drawings updated for the same

A3.9
Test Results OK?
Design Changes related to Non-standard requirement from customer which has been reviewed & accepted as referred in procedure for contract review are carried out as under:

- Design Changes are worked out & where required, the same are verified and reviewed to ensure that they meet the changed requirements and to identify any problems in implementing the changes.
- Necessary instructions for implementing such changes is given to various Departments through Memo for Non-standard requirements including any changes required in the inspection and testing of the product wherever necessary.
- The changes are validated through in-process final testing and recorded in the test report wherever practicable and applicable.
### RECORDS TABLE

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>FILE REFERENCE</th>
<th>FILE DESCRIPTION</th>
<th>LOCATION</th>
<th>MAINTAINED BY</th>
<th>RETENTION PERIOD</th>
</tr>
</thead>
</table>
| 1.      | DD 00 - 801    | "Design Record File".  
-Design Plan  
(DD00 - 401)  
-Design Review Record  
(DD00 - 403)  
-Design Verification /  
Validation Record | R & D Department | R & D Head | 3 Years |
| 2.      | DD 00 - 802    | "Design Change File".  
-Design Changes  
-DD00 - 402)  
-Design Change Verification /  
Validation Record | R & D Department | R & D Head | 3 Years |