

Divisional Manufacturing Engineering

Date	ISSUE/ REVISION DESCRIPTION
10-17-06	<p>Description of Revision: Changing a site-specific procedure (old Thermal ME 622) into a divisional procedure.</p> <p><u>Effective Date 12-01-06</u></p>
11-13-07	<p>Description of Revision: Addition of QCIs to the procedure and to the Equipment/Process Validation Check List</p> <p><u>Effective Date 12-03-07</u></p>
3-20-08	<p>Change to Section 5.1 Flowchart. Run requirement changed from “8 hours” to “8 hours preferred, lesser durations to be manager approved prior to the run.” Added Section 7.2 – DBS ME 3.9.4-2 Create Tooling Information for 1810 VTAM Process. Added record retention information for DBS ME 3.9.4-2.</p> <p><u>Effective Date 4-14-08</u></p>
7-31-08	<p>Change to DBS ME 3.9.4-1 Equipment/Process Validation Checklist, Section 1 – General Information & Plan, to include plan for machine qualification and manager approval.</p> <p><u>Effective Date 7-31-08</u></p>
5-5-09	<p>Change to DBS ME 3.9.4-1 Equipment/Process Validation Checklist – Section 3-23, 3-24, 3-25 due to Capital Finance move from MTC to Genpact and changes to the tooling rebill process. DBS ME 3.9.4-2 has been eliminated.</p> <p><u>Effective Date 5-8-09</u></p>
9-29-09	<p>Change to Section 8 to include AIAG’s core tools as reference, local procedures for updating documents on the floor and relevant customer documents. Change to DBS ME 3.9.4-1 Equipment/Process Validation Checklist – Section 3-17 to reference local procedures when updating the documents on the floor.</p> <p><u>Effective Date 10-1-09</u></p>
8-12-10	<p>Update to add the Machinery and Equipment Health and Safety Checklist DBS ME 3.9.4-2 and clarify H&S Process in more detail.</p> <p><u>Effective Date 8-20-10</u></p>

Manufacturing Systems Qualification

DBS ME 3.9.4

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ISSUE/ REVISION APPROVAL

	Title/ Function	Name	Signature	Date
Prep.	Staff Mfg. Engineer	Sharon Micallef	On file	8/12/2010
Appr.	Chief Manufacturing Engineer	David Kauppila	On file	8/12/2010
Appr.	Director of Engineering	Steven Kiefer	On file	8/12/2010

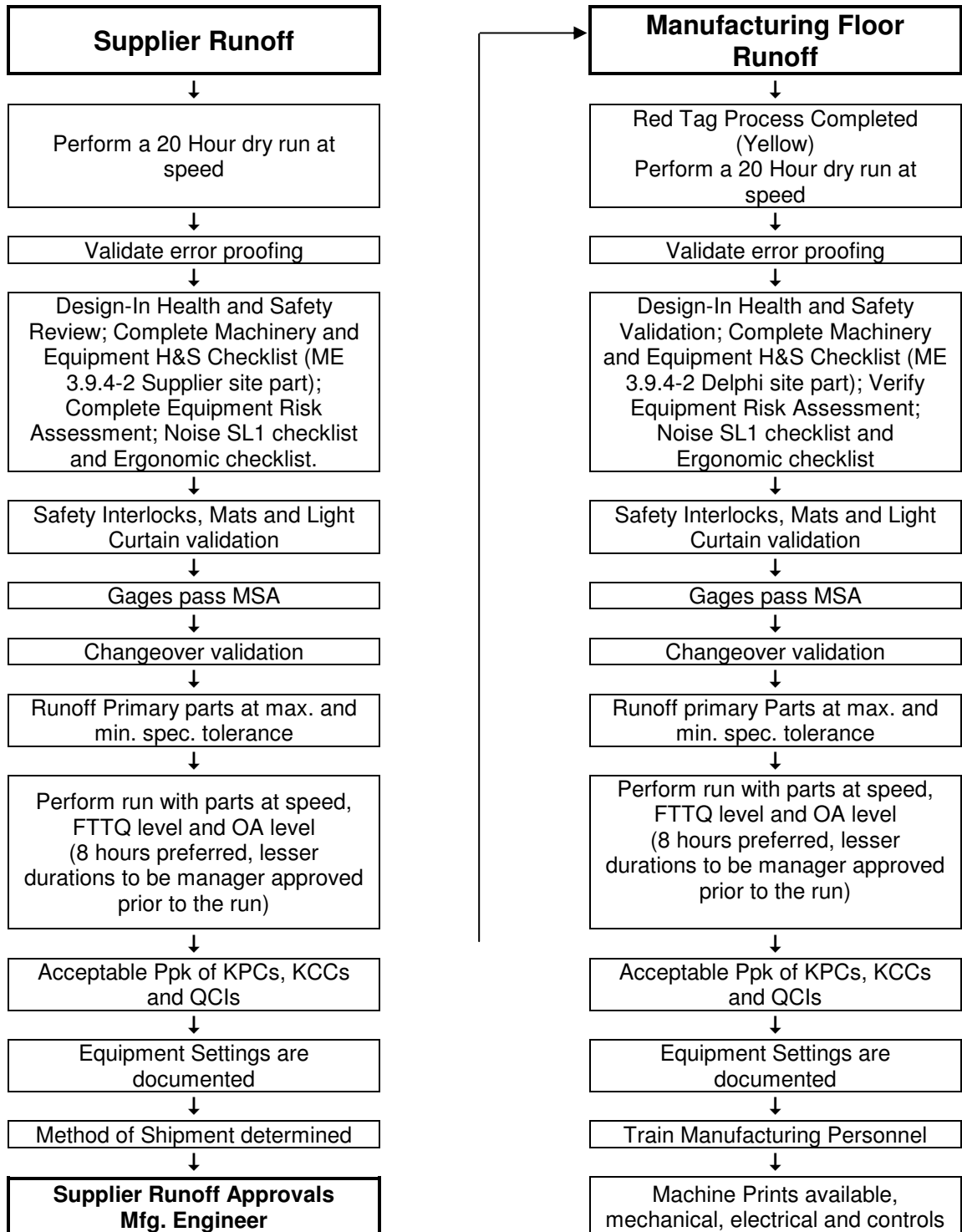
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- 1.0 Purpose:
 - 1.1 To ensure that equipment is thoroughly and properly validated during tryout.
- 2.0 Scope:
 - 2.1 This procedure applies to Manufacturing Engineering.
- 3.0 Responsibility:
 - 3.1 The Responsibility for the implementation of the procedure is the Manufacturing Engineering Manager for their respective product lines.
- 4.0 Definitions:
 - 4.1 KCC – Key Control Characteristic
 - 4.2 FTTQ – First Time Through Quality
 - 4.3 KPC – Key Product Characteristic
 - 4.4 OA – Operational Availability
 - 4.5 MSA – Measurement System Analysis
 - 4.6 PFMEA – Process Failure Mode and Effects Analysis
 - 4.7 QCI – Quality/Customer Interface Characteristic

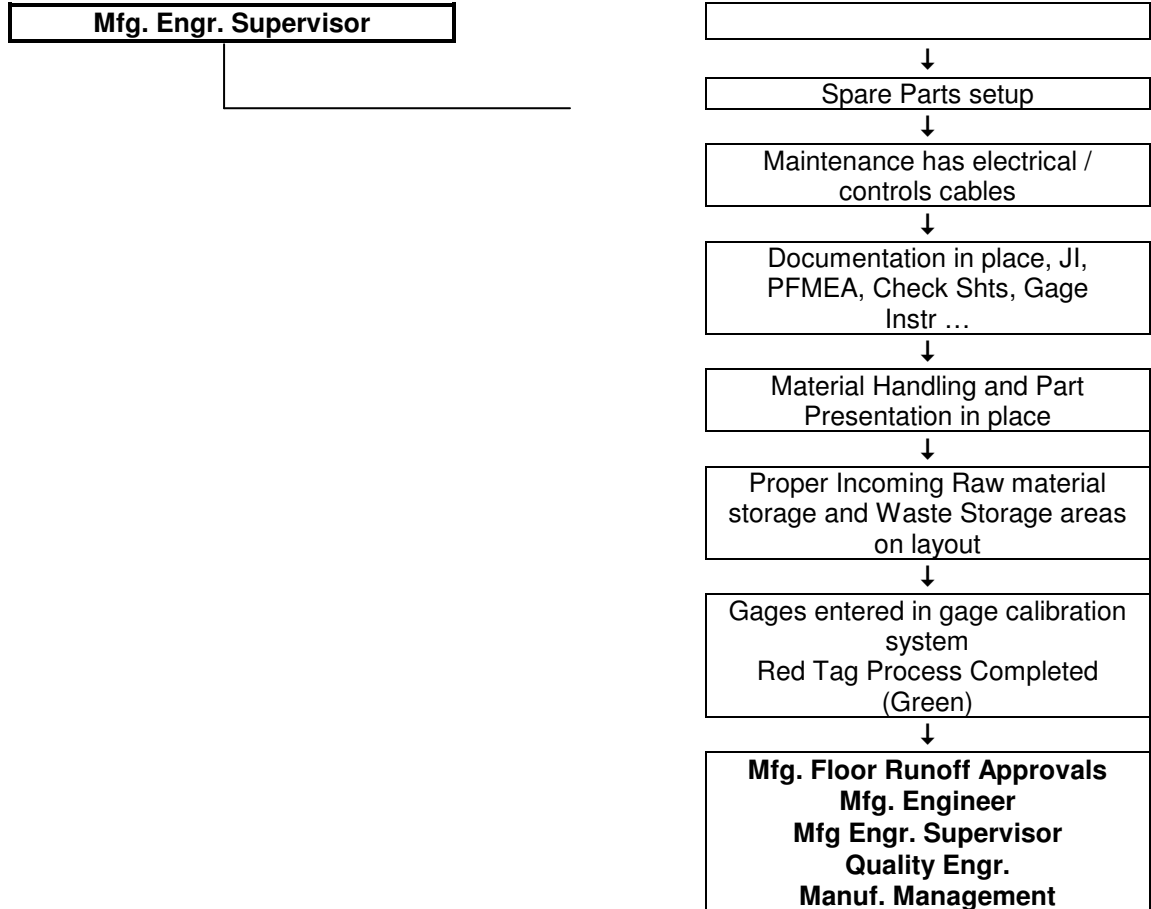
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5.0 Procedure:

5.1 Flowchart



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6.0 Documentation:

6.1 N/A

7.0 Control of Records:

7.0 DBS ME 3.9.4-1 – Equipment/Process Validation Checklist

7.1 DBS ME 3.9.4-2 – Equipment / Process Health and Safety Checklist

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Record (Id)	Collection	Indexing	Access	Filing	Storage	Maintenance	Disposition
Name of record (what)	When/Where records are gathered	How are records retrieved	Who has access to records	How/Who and Where records are filed	How and where records are stored	How records are maintained	When, who and how records are disposed.
Equipment/ Process Validation Checklist DBS ME 3.9.4-1	Manager files after approved tryout	Upon request	ME Manager	By ME Manager and stored in office file	By ME Manager and stored in office file	Manually maintained as changes occur	Maintain for 3 years as a minimum, ME Manager, Shred
Machinery and Equipment H&S checklist DBS ME 3.9.4-2	At Supplier and at Delphi Plant for validation of equipment	Access to EH&S warehouse	All employees with sharepoint access	By ME, electronic on the EH&S warehouse site	Electronically stored on the EH&S warehouse site	Manually maintained as changes occur	Saved electronically for reference after program life.

8.0 Reference(s):

- 8.0 The appropriate version of AIAG core tools, including:
 - 8.0.1 Advanced Product Quality Planning and Control Plan (APQP)
 - 8.0.2 Production Part Approval Process (PPAP)
 - 8.0.3 Measurement System Analysis (MSA)
 - 8.0.4 Potential Failure Mode and Effects Analysis (FMEA)
 - 8.0.5 Statistical Process Control (SPC)
- 8.1 Reference appropriate plant procedures for the floor documentation.
- 8.2 Other references may be used as stipulated by Customers.
- 8.3 Delphi Design-in H&S Specification DA-2006
- 8.4 ME 3.9.4-1 MSQ Validation checklist
- 8.5 ME 3.9.4-2 Delphi Thermal H&S Checklist
- 8.6 Delphi SL1 Noise checklist (Supplier and at Manufacturing site)
- 8.7 Delphi Equipment Risk Assessment form
- 8.8 EH&S warehouse (link from ME SharePoint) for storage of EH&S documents