

## **VALIDATION LEVEL CHECKLIST**

CUSTOMER:	PART N	NAME:	PART NUMBER:	REVISION:
Level 0 (Minimum Required)	Level 1 (Standard Process)	Level 2	Level 3	Level 4
SECTION 1 OVERALL SUMMARY	SECTION 1 OVERALL SUMMARY	SECTION 1 OVERALL SUMMARY	SECTION 1 OVERALL SUMMARY	SECTION 1 OVERALL SUMMARY
SIGNED SAMPLE APPROVAL FORM	SIGNED SAMPLE APPROVAL FORM	SIGNED VALIDATION PROTOCOL AND REPORT	SIGNED VALIDATION PROTOCOL AND REPORT	SIGNED VALIDATION PROTOCOL AND REPORT
DEVIATIONS (IF APPLICABLE)	DEVIATIONS (IF APPLICABLE)	DEVIATIONS (IF APPLICABLE)	DEVIATIONS (IF APPLICABLE)	DEVIATIONS (IF APPLICABLE)
SECTION 2 APPLICABLE DOCUMENTATION	SECTION 2 APPLICABLE DOCUMENTATION	SECTION 2 APPLICABLE DOCUMENTATION	SECTION 2 APPLICABLE DOCUMENTATION	SECTION 2 APPLICABLE DOCUMENTATION
DRAWING	DRAWING	DRAWING	DRAWING	DRAWING
NTERNAL INSPECTION DOCUMENTS ORS & IPI)	INTERNAL INSPECTION DOCUMENTS (ORS & IPI)	INTERNAL INSPECTION DOCUMENTS (ORS & IPI)	INTERNAL INSPECTION DOCUMENTS (ORS & IPI)	INTERNAL INSPECTION DOCUMENTS (ORS & IPI)
ADDITIONAL REQUESTED DOCUMENTS	MATERIAL C of C	FROZEN VALIDATED PROCESS	FROZEN VALIDATED PROCESS	FROZEN VALIDATED PROCESS
	ADDITIONAL REQUESTED DOCUMENTS	CALIBRATION CERTS (MEASUREMENT EQUIPMENT)	CALIBRATION CERTS (MEASUREMENT EQUIPMENT)	CALIBRATION CERTS (MEASUREMENT EQUIPMENT)
	SECTION 3 OPERATIONAL QUALIFICATION	MATERIAL C of C	MATERIAL C of C	MATERIAL C of C
	BUBBLE DRAWING	ADDITIONAL REQUESTED DOCUMENTS	ADDITIONAL REQUESTED DOCUMENTS	ADDITIONAL REQUESTED DOCUMENTS
	3PC FAI PER CAVITY	SECTION 3 OPERATIONAL QUALIFICATION	SECTION 3 INSTALLATION QUALIFICATION	SECTION 3 RISK ANALYSIS & MITIGATION
		BUBBLE DRAWING	MOLD INSTALLATION QUALIFICATION CHECKLIST (FRM8.5-3)	PROCESS FLOW DIAGRAM
		3PC FAI PER CAVITY (OQ NOM)	MOLD SET-UP & START-UP CHECKLIST (FRM8.5-4)	PFMEA (PROCESS FAILURE MODE AND EFFECT ANALYSIS)
		30PC CAPABILITY ANALYSIS (OQ HIGH, LOW, NOM)	PM WORKSHEETS (MFG EQUIPMENT USED)	CONTROL PLAN
		SECTION 4 PERFORMANCE QUALIFICATION	SECTION 4 OPERATIONAL QUALIFICATION	SECTION 4 INSTALLATION QUALIFICATION
		30PC CAPABILITY ANALYSIS (PQ 1)	BUBBLE DRAWING	MOLD INSTALLATION QUALIFICATION CHECKLIST (FRM8.5-3)
		WORK ORDER / BOM (PQ 1)	3PC FAI PER CAVITY (OQ NOM)	MOLD SET-UP & START-UP CHECKLIST (FRM8.5-4)
30,000		*******	30PC CAPABILITY ANALYSIS (OQ HIGH, LOW, NOM)	PM WORKSHEETS (MFG EQUIPMENT USED)
Approval Signatures		***	SECTION 5 PERFORMANCE QUALIFICATION	SECTION 5 MEASUREMENT SYSTEM ANALYSIS
			30PC CAPABILITY ANALYSIS (PQ 1, PQ 2, PQ 3)	GAGE R&R(S) (ALL MEASURING EQUIPMENT USED)
			WORK ORDER / BOM (PQ 1, PQ 2, PQ 3)	TYPE 1 [ OP] [ REP] [ SAMPLES] [ CTQ's]
				TYPE 2 [ OP] [ REP] [ SAMPLES] [ CTQ's]
TechNH Representative Signature	Print Name	Today's Date		SECTION 6 OPERATIONAL QUALIFICATION
				BUBBLE DRAWING
				3PC FAI PER CAVITY (OQ NOM)
				30PC CAPABILITY ANALYSIS (OQ HIGH, LOW, NOM)
Customer Representative Signature	Print Name	Today's Date		SECTION 7 PERFORMANCE QUALIFICATION
		]		30PC CAPABILITY ANALYSIS (PQ 1, PQ 2, PQ 3)



WORK ORDER / BOM (PQ 1, PQ 2, PQ 3)