

Special Process: Mole	ding System Asses	ssment	
Facility Name: Armada Rubber M Address:	Mfg. Co.		
24586 Armada Ridge Road			
Armada MI 48005			
Phone Number:586-784-9135 Fax Number:		Type(a) of Molding Processes	at this Escilitur
rax Number.		Type(s) of Molding Processes	s at this facility.
Number of Molding Employees a	at this Facility:		
Captive Molder (Y/N):N			
Number of Molding Employees a	at this Facility:		
62 Date of Assessment: 10/10/2024	4		
Date of Assessment. 10/10/2024	+		
Date of Previous Assessment:	10/11/2023		
		Process Table E	
		Transfer Molding	
		Process Table H	
		Part Inspection & Testing	
Current Quality Certification(s): I Date of Re-assessment (if neces			
Personnel Contacted: Name: Don Edwards	Title: GM	Phone: 586.784.9135	Email: DonEdwards@Armadarubber.com
tamo. Bon Lawarao	Title. Oil	I Hone: coo.: a ha tec	Email: SonEavarase, imagarasson.com
Auditors/Assessors:			
Name: Jeramy Evely	Company: Armada Rubb	per MFG Co Phone: 586.784.9135	Email: jevely@armadarubber.com
Number of "Not Satisfactory" Fin	ndings:0		
Number of "Needs Immediate A	ction" Findings:0		
Number of "Fail" Findings in the	Job Audit(s):		
		-	
Number of Process Table Items	not meeting Minimum Regu	uirements:	
· · · · · · · · · · · · · · · · · · ·		-	

	Special Process: Molding System Assessment (General Facility Overview)										
						Assessment					
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action				
	Section 1 - Management Responsibility and Quality Planning										
1.1	Is there a dedicated and qualified molding professional on-site?	To ensure readily available expertise, there shall be a dedicated and qualified molding person on the site. This individual shall be a full-time employee and the position shall be reflected in the organization chart. A job description shall exist identifying the qualifications for the position including chemical and molding knowledge. The qualifications shall include a minimum of 5 years experience in molding operation or a combination of a minimum of 5 years of formal technical education and molding experience.	Over 100 years collective experience		Satisfactory						
1.2	Does the molder perform advanced quality planning?	The molder shall incorporate a documented advanced quality planning procedure. A feasibility study shall be performed and internally approved for each new part or process. Similar parts can be grouped into part families for this effort as defined by the molder. After the part approval process is approved by the customer, no process changes are allowed unless approved by the customer. The molder shall contact the customer when clarification of process changes is required. This clarification of process changes shall be documented.	Process is in place		Satisfactory						



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
1.3	Are the molder's FMEA's up to date and reflecting current processing?	The molder shall incorporate the use of a documented Failure Mode and Effects Analysis (FMEA) procedure and ensure the FMEAs are updated to reflect current part quality status. The FMEA shall be written for each part or part family or they may be process-specific and written for each process. In any case, they shall address all process steps from part receipt to part shipment and all key molding process parameters as defined by the molder. A cross-functional team shall be used in the development of the FMEA. All special characteristics, as defined by the molder and its customers, shall be identified, defined, and addressed in the FMEA.	PFMEA is in place, family style.		Satisfactory		
1.4	Are molding process Control Plans up to date and reflecting current processing?	The molder shall incorporate the use of a documented Control Plan procedure and ensure the Control Plans are updated to reflect current controls. The Control Plans shall be written for each part or part family or they may be process-specific and written for each process. In any case, they shall address all process steps from part receipt to part shipment and identify all equipment used and all key molding process parameters as defined by the molder. A cross-functional team, including a production operator, shall be used in the development of Control Plans, which shall be consistent with all associated documentation such as work instructions, shop travelers, and FMEAs. All special characteristics, as defined by the molder and its customers, shall be identified, defined, and addressed in the Control Plans. Sample sizes and frequencies for evaluation of process and product characteristics shall also be addressed consistent with the minimum requirements listed in the Process Tables.	Control Plan is in place, family style.		Satisfactory		

					-	Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
1.5	Are all molding related and referenced specifications current and available? For example: SAE, AIAG, ASTM, General Motors, Ford, and Chrysler.	To ensure all customer requirements are both understood and satisfied, the molder shall have all related molding and customer referenced standards and specifications available for use and a method to ensure that they are current. Such standards and specifications include, but are not limited to, those relevant documents published by SAE, AIAG, ASTM, General Motors, Ford, and Chrysler. The molder shall have a process to ensure the timely review, distribution, and implementation of all customer and industry engineering standards and specifications and changes based on customer-required schedule. This process shall be executed as soon as possible and shall not exceed two weeks. The molder shall document this process of review and implementation, and it shall address how customer and industry documents are obtained, how they are maintained within the molder, how the current status is established, and how the relevant information is cascaded to the shop floor within the two-week period. The molder shall identify who is responsible for performing these tasks.			Satisfactory		
1.6	Are all molding related internal and external best practices documented and maintained?	The molder should have a documented process and system for maintaining best practices obtained through lessons learned or from industry knowledge.	Documented process is in place		Satisfactory		



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
1.7	Is there a written process specification for all active processes?	The molder shall have written process specifications for all active processes and identify all steps of the process including relevant operating parameters. Examples of operating parameters include process temperatures, cycle times, etc. Such parameters shall not only be defined, they shall have operating tolerances as defined by the molder in order to maintain process control. All active processes should have a written process specification. These process specifications may take the form of work instructions, job card, start-up sheet, or other similar documents.	specification		Satisfactory		
1.8	Has a valid product capability study been performed initially and after process change?	To demonstrate each process is capable of yielding acceptable product, the molder shall perform product capability studies for the initial validation of each process, after relocation of any process equipment, and after a major rebuild of any equipment. The molder shall define what constitutes a major rebuild. Initial product capability studies shall be conducted for all molding processes per line as defined in scope of work and in accordance with customer requirements. Capability study techniques shall be appropriate for the molding product characteristics, e.g., molding thickness, part weight, etc. Any specific customer requirements shall be met. In the absence of customer requirements, the molder shall establish acceptable ranges for measures of capability. An action plan shall exist to address the steps to be followed in case capability indices fall outside customer requirements or established ranges.	Capability is performed for each new part.		satisfactory		



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
1.9	Does the molder collect and analyze data over time, and react to this data? Are records available?	The analysis of products and processes over time can yield vital information for defect prevention efforts. The molder shall have a system to collect, analyze, and react to product or process data over time. Methods of analysis shall include ongoing trend or historical data analysis of special product or process parameters/characteristics. The molder shall determine which parameters/characteristics to include in such analysis. All process control and testing records must be retained for a minimum of one calendar year after the year in which they were created.	Yes, test results for each batch is measured and retaineds		Satisfactory		
	Are internal assessments being completed on an annual basis, at a minimum, incorporating AIAG Molding System Assessment?	The molder shall conduct internal assessments on an annual basis, at a minimum, using the AIAG Molding System Assessment. Concerns shall be addressed in a timely manner.	Yes, per IATF 16949		Satisfactory		
1.11	Is there a system in place to authorize reprocessing and is it documented?	The quality management system shall include a documented process for reprocessing that shall include authorization from a designated individual. The reprocessing procedure shall describe product characteristics for which reprocessing is allowed as well as those characteristics for which reprocessing is not permissible. All reprocessing activity shall require a new processing control sheet issued by qualified technical personnel denoting the necessary molding modifications. Records shall clearly indicate when and how any material has been reprocessed. The Quality Manager or a designee shall authorize the release of reprocessed product.	Vulcanized rubber cannot be reused		Satisfactory		
1.12	Does the Quality Department review, address, and document customer and internal concerns?	The quality management system shall include a process for documenting, reviewing, and addressing customer concerns and any other concerns internal to the molder. A disciplined problem solving approach shall be used.	Yes		Satisfactory		



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
1.13	Is there a continual improvement plan applicable to each process defined in the scope of the assessment?	The molder shall define a process for continual improvement for each molding process identified in the scope of the Molding System Assessment. The process shall be designed to bring about continual improvement in quality and productivity. Identified actions shall be prioritized and shall include timing (estimated completion dates). The molder shall show evidence of program effectiveness.	Yes		Satisfactory		
1.14	Does the Quality Manager or designee authorize the disposition of material from quarantine status?	The Quality Manager or designee is responsible for authorizing and documenting appropriate personnel to disposition quarantine material.	Yes		Satisfactory		
1.15	Are there procedures or work instructions available to molding personnel that define the molding process?	There shall be procedures or work instructions available to molding personnel covering the molding process. These procedures or work instructions shall include methods of addressing potential emergencies (such as power failure), equipment start-up, equipment shut-down, product segregation (See 2.8), product inspection, and general operating procedures. These procedures or work instructions shall be accessible to shop floor personnel.	Yes, work instructions are available		Satisfactory		
1.16	Is management providing employee training for molding?	The molder shall provide employee training for applicable molding operations. All employees, including backup and temporary employees, shall be trained. Documented evidence shall be maintained showing the employees trained and the evidence shall include an assessment of the effectiveness of the training. Management shall define the qualification requirements for each function, and ongoing or follow-up training shall also be addressed.	Yes, records are available		Satisfactory		



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
1.17	to ensure that all key	The molder shall maintain a responsibility matrix identifying all key management and supervisory functions and the qualified personnel who may perform such functions. It shall identify both primary and secondary (backup) personnel for the key functions (as defined by the molder). This matrix shall be readily available to management at all times.	Yes		Satisfactory		
1.18	Is there a preventive maintenance program? Is maintenance data being utilized to form a predictive maintenance program?	The molder shall have a documented preventive maintenance program for key process equipment (as identified by the molder). The program shall be a closed-loop process that tracks maintenance efforts from request to completion to assessment of effectiveness. Equipment operators shall have the opportunity to report problems, and problems shall also be handled in a closed-loop manner. Company data, e.g., downtime, quality rejects, first time-through capability, recurring maintenance work orders, and operator-reported problems, shall be used to improve the preventive maintenance program. Maintenance data shall be collected and analyzed as part of a predictive maintenance program.	Yes		Satisfactory		
1.19	Has the molder developed a critical spare parts list, and are the parts available to minimize production disruptions?	The molder shall develop and maintain a critical spare parts list and shall ensure the availability of such parts to minimize production disruptions.			Satisfactory		



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
		Section 2 - Floor and Mate	erial Handling Responsibility	y			
2.1	Does the facility ensure that the data entered in the receiving system matches the information on the customer's shipping documents?	Documented processes and evidence of compliance shall exist, e.g., shop travelers, work orders, etc. The facility shall have a detailed process in place to resolve receiving discrepancies.	N/A		Satisfactory		
2.2	Is product clearly identified and staged throughout the molding process?	Procedures for part and container identification help to avoid incorrect processing or mixing of lots. Appropriate location and staging within the facility also help to ensure that orders are not shipped until all required operations are performed. Customer product shall be clearly identified and staged throughout the molding process. Non-molded, in-process, and finished product shall be properly segregated and identified. All material shall be staged in a dedicated and clearly defined area.	Yes, part tagging system in place		Satisfactory		
	Is molder using adequate FIFO system for material and product?	There shall be a procedure that ensures a FIFO system is utilized.	Yes, via serial numbers / date code.		Satisfactory		
2.4	Is lot traceability and integrity maintained throughout all processes?	Out-going lot(s) shall be traceable to the incoming lot(s). The discipline of precisely identifying lots and linking all pertinent information to them enhances the ability to do root cause analysis and continual improvement.	Yes, via serial numbers		Satisfactory		



				Assessment			
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
2.5	Are procedures adequate to prevent movement of non-conforming product into the production system?	The control of suspect or non-conforming product is necessary to prevent inadvertent shipment or contamination of other lots. Procedures shall be adequate to prevent movement of non-conforming product into the production system. Procedures shall exist addressing proper disposition, product identification and tracking of material flow in and out of hold area. Non-conforming hold area shall be clearly designated to maintain segregation of such material.	Yes, red tag system in place		Satisfactory		



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
2.6	Is there a system to identify trap points in the entire process to reduce risk of mixed parts (inappropriate, unfinished or improperly molded parts)?	The molder shall have documented procedures to identify and monitor trap points for each process/equipment. Monitoring of potential trap points shall occur for every part changeover.	Yes, use of colored tubs		Satisfactory		
1 2/	Are containers free of inappropriate material?	Containers handling customer product shall be free of inappropriate material. After emptying and before reusing containers, containers shall be inspected to ensure that all parts and inappropriate material have been removed. The source of inappropriate material shall be identified and addressed. This is to ensure that no nonconforming molded parts or inappropriate material contaminate the finished lot.	Yes		Satisfactory		
2.8	Are operators trained in material handling, containment action and product segregation in the event of an equipment emergency including power failure?	Unplanned or emergency downtime greatly raises the risk of improper processing. Operators shall be trained in material handling, containment action, and product segregation in the event of an equipment emergency including power failure. Training shall be documented. Work instructions specifically addressing potential types of equipment emergencies and failures shall be accessible to and understood by equipment operators. These instructions shall address containment/reaction plans related to all elements of the process. Evidence shall exist showing disposition and traceability of affected product.	Standard training procedure		Satisfactory		
	Is the handling, storage and packaging adequate to preserve product quality?	The molder's in-process handling and shipping process shall be assessed for risk of part damage or other quality concerns.	Yes		Satisfactory		



						Assessment	
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action
2.10	Are plant cleanliness, housekeeping, environmental and working conditions conducive to control and improved quality?	Plant cleanliness, housekeeping, environmental, and working conditions shall be conducive to controlling and improving quality. The molder should evaluate such conditions and their affect on quality. A housekeeping policy shall be clearly defined and executed.	Yes		Satisfactory		
2.11	frequencies specified in	Process control parameters shall be monitored per frequencies specified in Process Tables. Computer monitoring equipment with alarms and alarm logs satisfy the verification requirement. A designated floor person shall verify the process parameters.	N/A		Satisfactory		
2.12	Are out of control/specification parameters reviewed and reacted to?	There are documented reaction plans to both out of control and out of tolerance process parameters. There is documented evidence that reaction plans are followed.	Dimensions are not monitored		Satisfactory		
2.13	Are Test Frequencies performed as specified in Process Tables?	Test Frequencies shall be performed as specified in Process Tables. Refer to Process Tables	Yes, for material specifications		Satisfactory		
2.14	Is product test equipment verified?	Test equipment shall be verified/calibrated per applicable customer specific standard or per an applicable consensus standard, e.g., ASTM, SAE, ISO, NIST, etc. Verification/calibration results shall be internally reviewed, approved and documented. Refer to Process Tables for frequency of checks.	Yes, evidence is available		Satisfactory		
2.15	Lighting of inspection area	Lighting in the inspection area shall be sufficient to allow the evaluation of all part surfaces. The lighting shall be arranged to preclude spot lighting, glare or shadows. There can be no moving or distracting reflections on the surfaces to be evaluated.	Yes		Satisfactory		



	Special Process: Molding System Assessment (General Facility Overview)								
						Assessment			
Question Number	Question	Requirements and Guidance	Objective Evidence	N/A	Satisfactory	Not Satisfactory	Needs Immediate Action		



Section 3 - Job Audit - Finished Product Review

Job Identity:

Customer: General Motors

Shop Order Number: 17475

Part Number: 17475

Part Description: Clip - S/D

Molding Requirements: Per Drawing

Question #	Job Audit Question	Related Molding System Assessment Question #	Customer or Internal Requirement	Job (Shop) Order or Reference Documentation Requirement	Actual Condition (Objective Evidence)	Pass / Fail / N/A
3.1	Is contract review and advanced quality planning, FMEA, Control Plans, etc., in place and performed by qualified individuals?	1.1 1.2 1.3 1.4 1.6	Internal	N/A	Actual documents	Pass
3.2	Does the molder have the proper customer specifications for the part?	1.5	Customer	N/A	Part drawing	Pass
1 33	Is there documented evidence of Receiving Inspection?	2.1	Internal	QP-860-100	Actual documents	Pass
3.4	Is material identification (part numbers, lot numbers, contract numbers, etc.) maintained throughout the molding process?	2.2 2.3 2.4	Internal	QP-860-300	Observation	Pass
3.5	Is the proper procedure or process specification used? Refer to Process Tables for specific parameters. List parameters that were verified in this audit in the spaces provided below.	1.5 1.6 2.1 2.11 2.13	Internal	QP-860-300	Observation	Pass

Section 3 - Job Audit - Finished Product Review

Job Identity:	
Customer:	General Motors
Shop Order Number:	17475
Part Number:	17475
Part Description:	Clip - S/D
Molding Requirements:	Per Drawing

Question #	Job Audit Question	Related Molding System Assessment Question #	Customer or Internal Requirement	Job (Shop) Order or Reference Documentation Requirement	Actual Condition (Objective Evidence)	Pass / Fail / N/A	
	Process #1:						
	Process #2:						
	What are the product inspection requirements?	1.5 2.13 2.14	Each part may have one or more requirements determined by the molding specification. Parts must meet each requirement. List each requirement below and validate. (Listed below are some examples)				
3.6.1	Requirement: Weight		N/A				
	Test Method:						
	Test frequency or quantity:						
	Selection of samples:						
	Specification:						



Section 3 - Job Audit - Finished Product Review

Job Identity:	
Customer:	General Motors
Shop Order Number:	17475
Part Number:	17475
Part Description:	Clip - S/D
Molding Requirements:	Per Drawing

Question #	Job Audit Question	Related Molding System Assessment Question #	Customer or Internal Requirement	Job (Shop) Order or Reference Documentation Requirement	Actual Condition (Objective Evidence)	Pass / Fail / N/A
3.6.2	Requirement: Color		N/A			
	Test Method(s):					
	Test frequency or quantity:					
	Selection of samples:					
	Specification:					
3.6.3	Requirement: Gloss		N/A			
	Test Method:					
	Test frequency or quantity:					
	Selection of samples:					
	Specification:					
3.6.4	Requirement: Flash		See drawing			
	Test Method(s):					
	Test frequency or quantity:					
	Selection of samples:					
	Specification:					

Section 3 - Job Audit - Finished Product Review

Job Identity:	
Customer:	General Motors
Shop Order Number:	17475
Part Number:	17475
Part Description:	Clip - S/D
Molding Requirements:	Per Drawing

Question #	Job Audit Question	Related Molding System Assessment Question #	Customer or Internal Requirement	Job (Shop) Order or Reference Documentation Requirement	Actual Condition (Objective Evidence)	Pass / Fail / N/A
3.6.5	Requirement: Dimension		See drawing			
	Test Method:					
	Test frequency or quantity:					
	Selection of samples:					
	Specification:					
3.6.6	Requirement: Appearance		N/A			
	Test Method:					
	Test frequency or quantity:					
	Selection of samples:					
	Specification:					
3.6.7	Requirement: Customer Specific		See drawing			
	Test Method(s):					
	Test frequency or quantity:					
	Selection of samples:					
	Specification:					

Section 3 - Job Audit - Finished Product Review

Job Identity:

Customer: General Motors

Shop Order Number: 17475

Part Number: 17475

Part Description: Clip - S/D

Molding Requirements: Per Drawing

Question #	Job Audit Question	Related Molding System Assessment Question #	Customer or Internal Requirement	Job (Shop) Order or Reference Documentation Requirement	Actual Condition (Objective Evidence)	Pass / Fail / N/A
Operator or	Inspector Responsibilities					
3.7	Were appropriate process steps signed off?	1.4 1.6 2.2 2.3 2.11	Yes			
3.8	Were all inspection steps, as documented in the Control Plan performed?	1.2 1.4	Yes			
3.9	Were steps/operations performed that were not documented in the Control Plan?	1.2 1.4 1.6	No			
	If additional steps were performed, were they authorized?	1.2 1.4 1.6 1.10 1.16	N/A			
3.11	Does the governing specification allow reprocessing or rework?	1.5 1.10	N/A			

Section 3 - Job Audit - Finished Product Review

Job Identity:

Customer: General Motors

Shop Order Number: 17475

Part Number: 17475

Part Description: Clip - S/D

Molding Requirements: Per Drawing

Question #	Job Audit Question	Related Molding System Assessment Question #	Customer or Internal Requirement	Job (Shop) Order or Reference Documentation Requirement	Actual Condition (Objective Evidence)	Pass / Fail / N/A					
3.12	If the order was certified, did the certification accurately reflect the process performed?	2.11 2.13	Yes								
1 313	Was the certification signed by an authorized individual?	1.16	Yes								
3.14	Are the parts and containers free of inappropriate objects or contamination?	2.6	Yes								
Packaging	Requirements										
3.15	Are packaging requirements identified?	2.6 2.7 2.9	Yes								
3.16	Are parts packaged to minimize mixed parts or damaged (for example, work flow or over-pack of container)?	2.6 2.7 2.9	Yes								
Shipping R	Shipping Requirements										
3.17	Were the parts properly identified?	2.3 2.9	Yes								
3.18	Were the containers properly labeled?	2.3 2.9	Yes								



All requirements given below are subordinate to customer specific requirements.

The customer may have additional requirements, e.g., inspection testing, greater frequencies, etc. When performing the job audit, the auditor shall verify molder is conforming to customer requirements.

Item #	Related Molding System Assessment Question #	Category/Process Steps	Type of Control		Monitoring Frequency		Observation/ Comments
			Minimum Requirement	Actual Condition	Minimum Requirement	Actual Condition	(Pass / Fail / N/A)
1.0		Receiving Inspection					
E1.1	1.4 2.1 2.13	Incoming material assessment procedure, covering onsite testing or acceptance of supplier testing, with criteria (i.e., melt flow, specific gravity, temperature recording).	Manual	Manual	Once per lot	Each shipment	Pass
E1.2	1.4 2.1 2.13	Incoming components assessment procedure, covering onsite testing or acceptance of supplier testing, with criteria (if applicable).	Manual	Manual	Once per lot	Each shipment	Pass
2.0		Compounding and Preforming (if applicable)					
E2.1	1.4 2.1 2.13	Purging all equipment and feeding system to avoid cross contamination.	Manual	Manual	End of run or long downtime, material change	Each Batch	Pass
E2.2	1.4 2.1 2.13	Compound property verification when applicable - For rubber and one part epoxy; preform, elongation, tensile strength, compression set, pre-cure rate, or rheology etc.	Manual	Manual	Per production lot	Each Batch	Pass
3.0		Storage & Handling					
E3.1	1.4 2.11 2.12	Stock rotation system in place for First in/First out (FIFO) and shelf-life.	Automatic/Manual	Manual	FIFO - per Lot Shelf life - pull for use		Pass
E3.2	1.4 2.11 2.12	Environment temperature and humidity for storage (if applicable).	Automatic	N/A	Continuous monitoring by controller or manual verification daily	N/A	N/A
E3.3	1.4 2.11 2.12	Temperature control during shipment from material supplier to cold storage area in plant (if applicable i.e.; one part epoxies).	Automatic	N/A	Continuous monitoring (i.e., by chart recorder)	N/A	N/A
E3.4	1.4 2.11 2.12	Material container remains sealed during warm up to room temperature (supplier recommendation).	Manual	N/A	Time stamp on container from time out of cold storage to when container is opened	N/A	N/A



All requirements given below are subordinate to customer specific requirements.

The customer may have additional requirements, e.g., inspection testing, greater frequencies, etc. When performing the job audit, the auditor shall verify molder is conforming to customer requirements.

Item #	Related Molding System Assessment Question #	Category/Process Steps	Type of Control		Monitoring Frequency		Observation/ Comments
			Minimum Requirement	Actual Condition	Minimum Requirement	Actual Condition	(Pass / Fail / N/A)
E3.5	1.4 2.11 2.12	Time exposed to room temperature when removed from cold storage area for production. Allowable usage time after room temperature is reached.		N/A	Continuous monitoring by controller or manual verification	N/A	N/A
E3.6	1.4 1.6 2.11 2.12	Partial container handling to ensure no contamination (closed container, clean environment)	Automatic/Manual	N/A	Continuous	N/A	N/A
E3.7	1.4 1.6 2.11 2.12	Partial container quantity	Automatic/Manual	Manual	Per Container	manual	Pass
4.0		Molding Process					
E4.1	1.4 1.15 2.11 2.12	There shall be a standardized startup procedure/checklist that defines things to do at start-up	Manual	Manual	Start-up and restart after long down time event	Start-up and restart after long down time event	Pass
E4.2	1.4 1.15 2.11 2.12	Production plan (machine, mold, materials, part style)	Manual	Manual	At start-up	Start-up and line checks	Pass
E4.3	1.4 1.15 2.11 2.12	Startup check (verify process settings against setup sheet)	Manual	Manual	At start-up, and after long down time event	At start-up, and after long down time event	Pass
E4.4	1.4 1.15 2.11 2.12	Mold cavity temperatures; variation between each cavity and set temperatures	Automatic	Automatic	Continuous, at start-up and after down time event.	Line checks	Pass
E4.5	1.4 1.15 2.11 2.12	Verification of preform size, or shape, or both	manual	N/A	Continuous	N/A	N/A
E4.6	1.4 1.15 2.11 2.12	Plasticization - Temperature (resin chamber), Transfer Speed, and Transfer Pressure	Automatic	Automatic	Continuous	Continuous	Pass
E4.7	1.4 1.15 2.11 2.12	Fill - Fill time and peak pressure	Automatic	Automatic	Continuous	Continuous	Pass



All requirements given below are subordinate to customer specific requirements.

The customer may have additional requirements, e.g., inspection testing, greater frequencies, etc. When performing the job audit, the auditor shall verify molder is conforming to customer requirements.

Item#	Related Molding System Assessment Question #	Category/Process Steps	Type of Control		Monitoring Frequency		Observation/ Comments
			Minimum Requirement	Actual Condition	Minimum Requirement	Actual Condition	(Pass / Fail / N/A)
E4.8	1.4 1.15 2.11 2.12	Hold - Hold pressure and hold time	Automatic	Automatic	Continuous	Continuous	Pass
E4.9	1.4 1.15 2.11 2.12	Cure Time	Automatic	Automatic	Continuous	Continuous	Pass
E4.10	2.12	Mold Closing speed	Automatic	Automatic	Continuous	Continuous	Pass
E4.11	1.4 1.15 2.11 2.12	Cavity surface cleanliness (no debris)	manual	Manual	Continuous	Continuous	Pass
E4.12	1.4 1.15 2.11 2.12	Pre-heat of components - If Insert molding required	Automatic	N/A	Continuous	N/A	N/A
E4.13	1.4 1.15 2.11 2.12	Pre-heat of resin pellets or compound - If applicable (per manufacturers recommendations)	Automatic	N/A	Continuous	N/A	N/A
E4.14	1.4 1.15 2.11 2.12	Hold - Cavity pressure (if applicable)	Automatic	N/A	Continuous	N/A	N/A
E4.15	1.4 1.15 2.11 2.12	Part weight (if applicable)	Manual	N/A	Once every 8 hours*	N/A	N/A
E4.16	1.4 1.15 2.11 2.12	First piece approval	Manual	Manual	Start-up, and restart after down time event	Start-up, and restart after down time event	Pass
E4.17	1.4 1.15 2.11 2.12	Shut down procedures	Manual	Manual	End of production or run	End of production or run	Pass
5.0		Quality Control					



All requirements given below are subordinate to customer specific requirements.

The customer may have additional requirements, e.g., inspection testing, greater frequencies, etc. When performing the job audit, the auditor shall verify molder is conforming to customer requirements.

Item#	Related Molding System Assessment Question #	Category/Process Steps	Type of Control		Monitoring Frequency		Observation/ Comments
			Minimum Requirement	Actual Condition	Minimum Requirement	Actual Condition	(Pass / Fail / N/A)
E5.1	1.4 2.11 2.12	Part weight	Manual	Manual	Start-up and once every 4 hours. For safety critical parts, start-up and once every hour	each packing batch	Pass
E5.2	1.4 2.11 2.12	Dimensions	Manual	Manual	Per cavity, start-up and once every 8 hours	annual	Pass
E5.3	1.4 2.11 2.12	Appearance (vs. boundary sample or per instruction)	Manual	Manual	Per cavity, start-up and once every 8 hours	Line checks	Pass
E5.4	1.4 2.11 2.12	Physical properties (if applicable)	Manual	Manual	Per cavity, start-up and once every 8 hours	Each Batch	Pass



PROCESS TABLE H - Part Inspection and Testing

All requirements given below are subordinate to customer specific requirements.

The customer may have additional requirements, e.g., inspection testing, greater frequencies, etc. When performing the job audit, the auditor shall verify molder is conforming to specifications or other requirements.

Note that not all tests are applicable to all molding processes.

Item #	Related Molding System Assessment Question #	Category/Process Steps	Monitoring Frequency		Observation/Comments		
		Dimension, Weight, Appearance,	Minimum Requirement	Actual Condition	(Pass / Fail / N/A)		
1.0		General					
		Dimensions					
		Appearance					
		Performance					
H1.1	1.4 2.9	Procedures are in place to prevent damage to the finish or part during the inspection and packaging processes	100%	100%	Pass		
H1.2	1.4	Appearance (flash, color and gloss, short shots, splay/burns, blister, sink marks, gate vestige, and other molding defects) of the molding shall be verified per specification and applications manual	First off by quality and 100% by operator	First off by quality and 100% by operator	Pass		
H1.3	1.4	Cracks, Weld line/Knit lines, and Whitening/ stress mark	First off and last off	N/A	N/A		
H1.4	1.4	Part identification	First off	First off	Pass		
H1.5	1.4	Manufacturing information	Daily Production Meeting Review	Daily Production Schedule	Pass		
H1.6	1.4	Dimensional check (e.g., Go-no go, Plug and Ring gage)	First off and once per shift	Attrbute only	Pass		
H1.7	1.4	Wall thickness	Per process table	N/A	N/A		
H1.8	1.4	General - Weight, Resin, Components, Porosity/Voids (if applicable)	First off	N/A	N/A		
H1.9	1.4	Performance	Per customer specifications	N/A	N/A		
H1.10	1.4	Environmental	Per customer specifications	N/A	N/A		