 UGEE CHEMICALS	PSG Department	Standard Operating SOP Procedure

PACKING IN-PROCESS CONTROL SOP			
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	Revision Date:	Maximum 2 years from Effective Date	
	Effective Date:	20 working days from the issuance date	

PURPOSE

- The purpose of Process control strategy is to ensure that we consistently produce quality products that meet required standards in terms of consumer/customer related attributes of product
- This is done by having in place good process design, approved standards, clearly defined centerlines and ranges, SOPs, personnel training and qualification and process monitoring through the use of various tools and techniques.
- This SOP outlines the control strategies involved in the total cycle of packing material receipt, storage, conversion to finished product (FP) and FP storage

RESPONSIBILITY

- **Process Engineer:** Ensures all personnel understand and comply with the Process Control Strategy.
- Ensures that the Process Control Strategy remains updated and functional.
- **Team Leader:** Ensures all operators in his team comply with the Process Control Strategy shiftily.
- **All operators:** Follow departmental Process Control Strategy SOP on a daily basis.

POTENTIAL RISKS

- Not Applicable

PPE REQUIRED

- Not Applicable

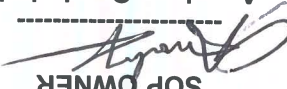

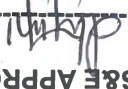

PROCEDURE

1. PROCESS CONTROL STRATEGY OVERVIEW

1.1 The Sources of Variation

The sources of variation in finished product quality can be attributed to the sum of variations in several independent variables impacting the finished product as shown in the expression below: variability is equal to the sum of several independent sources of variability (sigma)

$$\Sigma^2 \text{ FP product quality} = \Sigma^2 \text{ starting materials} + \Sigma^2 \text{ equipment} + \Sigma^2 \text{ process conditions} + \Sigma^2 \text{ repack} + \Sigma^2 \text{ changeover} + \Sigma^2 \text{ variable compliance}$$

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The process control strategy must control each individual source of variability. For each source of variability, we must implement a specific strategy to control it, the sources of variation in the process is:

- Packing Materials
- Startup/ Shut down / Brand/Size Changeover
- Repack
- Process/Equipment
- Variable Compliance

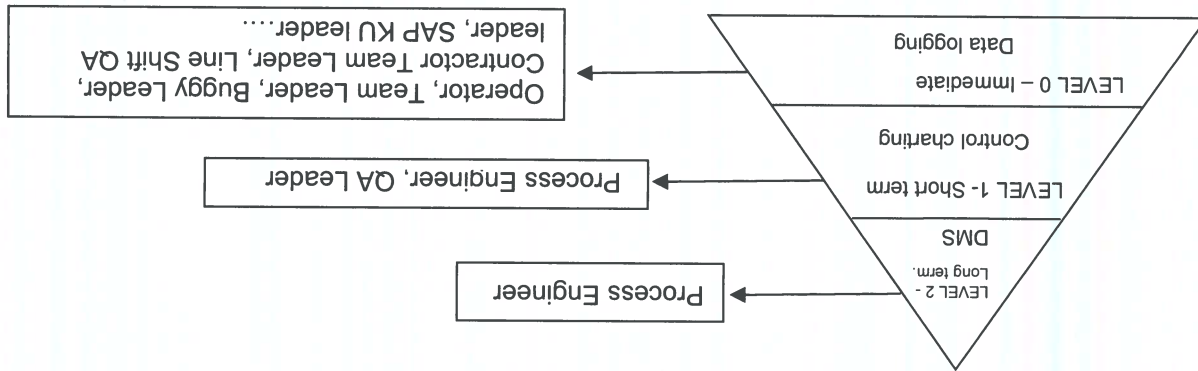
1.2 Product Quality Parameters

The following are the quality parameters to be monitored and controlled to achieve the Standard document requirements in the product by the PSG department.

Product Unit	Quality Parameter	Type	Standard Document
Bag	Weight	Variable	IPS / MPS
	Appearance	Attribute	TAMU – POLYBAG STANDARD
	Perforation	Attribute	
	Pinholes	Attribute	
	Photocell Location	Attribute	
	Seal Quality	Attribute	
	Code	Attribute	
Polywoven	Appearance	Attribute	TAMU – POLYWOVEN STANDARD
	Code	Attribute	
	Count	Attribute	
Pallet	Appearance	Attribute	TAMU – PALLETS STANDARD
	Stacking Pattern	Attribute	SPS

1.2 Three levels of process control strategy

There are 3 levels of process control strategy in use in PSG. All are introduced in this SOP



Level of Decision	Data analysis	Control tool	Measures	Frequency	Responsible
Level 0	Analyze single process parameters real time. Based on the value of these process parameters the operator does immediate interventions on the system.	- Centerline Audit sheets - Quality Alert - Process compliance failures - Process related quality alerts -Finished Product quality - Under pack - Over pack sheets control/TAMU	Shift Operator Line QC	Shiftily, daily	Operator
Level 1	Compare process parameters of previous runs with target settings in order to see relationships or trends, and based on this comparison the process Engineer decides to make short or medium time interventions. It is a predictive tool to avoid OOLs. In the case of OOLs, conduct a root cause analysis to fix the problem.	- Quality Window chart - Quality Alert Logs. - Yr tool - Loss Elimination tools.	Process Engineer QA Leader	Daily/Weekly	Engineer
Level 2	Use trending and gap analysis concepts to look for improvement opportunities in performance, this means looking for long term interventions on the system	-Line /WH Pickups ppm -Monthly Process Compliance report -Consumer complaints logs -Yr tool -Loss elimination tools	Process Engineer	Monthly	Engineer

2. PROCESS CONTROL STRATEGY LEVEL 0

2.1 Process Control Strategy Level 0 – PACKING MATERIALS

2.1.1 Material Receipt

Materials are received from the warehouse to the Packing department according to the Packing Material receipt & Finished Product Evacuation SOP.

The materials must conform to the Materials Receipt SOP checklist before being staged.

The materials are staged according to the Item GCAS Location in the staging area.

Control tool:

Packing material receipt checklist- SAP KU Leader

Measures:

Number of PM quality complaints on PM physical attributes

2.1.2 Material Usage / Material Change

Before materials are used on the packing line from the staging area, the machine operator must check the process order on SAP and use this to identify the pack material by IPMS tag. Product containing manufacturer splice during production will be scrapped by operator after the product had been captured by photocell and machine stop.

Control tool:

Machine stops due to splice: Photocell

Scraping of affected product (visual check): Machine operator

IPMS Tags on Packing Material- Machine Operator

Process Order- Team Leader

Measures:

Number of Q-Alerts for wrong packing material usage

Number of QIs for wrong packing material usage

2.2 Process Control Strategy Level 0 – RAW MATERIALS (powder)

2.2.1 Material Receipt

Powder is received from MSG to the Buggy floor according to the Buggy Handling SOP.

The materials must conform to the Buggy handling SOP requirements before being stored and placed on the various machines.

Control tool:

Buggy receipt cards.-Buggy Leader

Buggy Quality Window-Buggy Leader

Changeover checklist Shift QA leader & Team Leader

Measures:

100% within spec powder received and dumped on packing machines.

QIs due to wrong dumping of powder from buggy floor

QIs due to receipt of OOS powder on buggy floor

Number of repack done as a result of wrong dumping of powder from the buggy floor.

2.2.2 Material Usage

Before powder is dumped on the packing machines from the buggy floor, the buggy floor contractor must check that the powder GCAS matches the planned production according to the Buggy Handling SOP. He must also check that the powder is within density limits as received per batch.

No powder is dumped on a machine without the alignment of the packing machine operator on duty.

Control tool:

Buggy Receipt cards- Buggy Leader

Measures:

100% powder dumped on machine according to planned production and in concurrence with the machine operator.

2.3 Process Control Strategy Level 0 – CHANGE-OVER, START UP & SHUT DOWN

2.3.1 Change-over (Brand, Size, Reel and Ribbon change)

The changeover starts at the buggy floor where buggies containing the previous formulation are completely

emptied and filled with the new powder formulation. The PSG operator must follow the Line clearance & Change-over SOP. The operator must change the process settings to that of the new products and SKU according to the

target settings (centerlines) stated on the process audit sheet.

The line Shift QA leader must ensure all Quality window programs, weight limits and Packing standards associated with previous product are eliminated from the lane and replaced with the Quality window programs, weight

limits/guides and Packing standards for the new product.

The Team Leader signs off the line clearance checklist used for changeover. Machine operators scrap affected

products during reel change (splicing) by visually inspecting every product after splicing and taking off the affected product to the scrap bin. Machine operator checks that code is on print area, legible and complete after ribbon

change.

Control tool:

Line Clearance/Changeover checklist Shift QA leader & Team Leader

PDR checklist Shift QA leader

Scraping of product with splice: Machine operator

Checks for product code: Machine operator

Trouble shooting guide to make the correct adjustments to prevent process issues during start-up of the machine-

Line/Machine Operator

Process audit sheet - Line operator

Measures:

Number of stops 30mins after change over

Change over time

PR Loss due to change over in %

2.3.2 Startup and Shut down

The PSG operator must follow the Start-up & Shut down SOP of the department.

The Line Operator and the Shift QA leader must follow the TAMU SOP during the start of operation.

Control tool:

Start-up /shut down checklist- Line operator

Trouble shooting guide to make the correct adjustments for process issues during start-up of the machine-Line

Operator

Measures:

Number of Unplanned Stops at start-up and shutdown.

Startup/ shutdown time

PR Loss due to startup/ shutdown in %

2.4 Process Control Strategy Level 0 – PRODUCT REPACK

2.4.1 Product Repack

Repacking of product must be carried out by the Line operator according to the Repack Handling SOP.

2.4.2 Product Reblend

Powder with density out of limit received by the buggy floor at the BFS must be labeled "REBLEND" by the buggy floor operator and sent to the MSG Reblend floor according to the Buggy Handling SOP. For any unmarked buggy containing powder or which the quality/variant of the powder is unconfirmed, it must be labeled as reblend.

2.4.3 Product Scrapping

Off-spec product generated on the line is scrapped at the end of the line. The powder is recycled back to the machine by sending the powder to the buggy floor using big bag and move to the elevator to the buggy floor. Only the variant that is being produced on a line must be scrapped at the end of line. The recycled powder must be labeled "RECYCLE" and its variant stated on the label. The shift contractor team leader must follow the Spills and Powder Handling SOP.

2.4.4 Powder Cleanouts, Lumps/cakes and PVC products

Powder cleanouts, lumps/cakes by-products must be placed in a bag, clearly marked with the powder type, source and date and sent to the MSG re-melt floor to be received by the re-melt operator.

Control tool :

Reject Cabinet Operation SOP- Reject Cabinet Operator

Buggy Handling SOP-Buggy floor operator

Repack Handling SOP -Team Leader

Measures:

Daily Scrap %

Daily Process Reliability %

Q alerts/incidents related to repack.

2.5 Process control strategy level 0 – PROCESS/EQUIPMENT CONDITION

2.5.1 Buggy Operation control strategy

Buggy operation is carried out according to the Buggy handling SOP. The batches received are tracked on the quality window program on the buggy floor for density control and for traceability of batches. The buggy floor operator communicates the batch density to the MSG control room operator to make necessary adjustments to achieve target density.

Control Tool:

Operation is as per Buggy Handling SOP- Buggy Floor Operator
 Buggy floor QUALITY WINDOW- Density Station Operator
 Different colors per variant for buggy card-Buggy Floor Operator
 Powder GCAS labels per machine- Buggy Floor Operator

Measure:

Number of Q-alerts/QIs due to wrong buggy dumping
 Downtime due to No powder from buggy floor

2.5.2 Packing Operation

All Equipment and processes in the operation must be validated before use to ensure capability to consistently produce product. The validation must be done according to the validation CBA, as either Prospective or Concurrent; Retrospective validation is no longer used.
 For any change in the current operation, a change control must be raised and routed through the appropriate channels for approval before the change is executed.
 Proper EO must be conducted for any initiative before launch.

Control tool:

Approved Validation master plan- Process Engineer or Validation System Owner
 Change control approved before any change-Process Engineer
 Validation protocols followed for new equipment/process-Process Engineer

Measures:

Validation actions completion on time (%)

2.5.2.1 UVA 222 & Multilane

The UVA and multilane must be operated by qualified operators. For quality issues during the operation, the operator stops production and refers to the troubleshooting guide in other to fix the problem. The operator must ensure the RLS & CIL for the equipment is done according to the UVA & Multilane RLS & CIL Standards respectively.

The machine must be operated on approved centerlines as shown in the centerlines sheet and audited at specified frequency according to the Process Audit SOP.
Control Tool:

RLS standard is present and executed as per schedule (RLS checklist) - Machine Operator
CIL standard is present and executed as per schedule (CIL checklist) – Equipment owner.

Maintenance (TBM) schedule-PM Planner
Process Audit Sheet/Quality window- Machine Operator
SIMPTWW and Job Safety Analysis

Measures:

Daily Process Reliability (%)

Number of centerline OOL

Number of breakdowns per month

2.5.2.2 End of Line Operation

Products are packed according to the IPS and stacked according to the SPS for the product being packed. The cases are coded according to the Coding operation SOP.

Control:

Operations carried out as per SOP-Team Leader

Only qualified contractors must perform End of line operation- Contractor Leader

Measures:

Number of Q-alerts/QI from End of line activity (undercount, wrong secondary packaging (polywoven) usage, etc.)

2.5.3 Variable check

The Line QC must check the product weight for each lane according to the sampling plan and record the data in the Weight Sheet and quality window (QV) as defined in the Weight control SOP.

The weight is adjusted based on the status of the average weight; when the weight is below target, the sample is entered in the HMI to increase the turn-set, and when the weight is above target, the turn-set is decreased when adjusted.

Control tool:

Weight guide – Shift QA leader)

Weight sheet/Quality window- Line QC

Weight scales are calibrated on time as per schedule- Shift QA leader

Scale daily Calibration – Shift QA leader

Measures:

Daily Over pack (%)

%TU1 and %TU2 less than 2%

Daily Under pack

2.5.4 Attribute check

The shift/machine operator must follow the TAMU SOP for the sampling of products for attribute parameter checks. The team leader reacts based on the TAMU SOP, i.e., Stop and Sort to 100%

Whenever the Line QC, he informs the machine operator to make necessary adjustment or stop the machine, detects defective product, the machine operator fills a quality alert, and holds the batch to be sorted by the operator until no defective products are detected.

Control Tool:

Sampling done as per TAMU SOP-Machine Operator

TAMU Standards- Line Operator

TAMU checklist/Quality window- Line/Machine operator.

Measures:

Number of on hold event

Daily PPM report

2.6 Process control strategy level 0 – VARIABLE COMPLIANCE

2.6.1 Test Methods

All Test methods and packing standards must be approved before use in the operation
Control:

No un-approved standards on the line- Process Engineer/ QA Leader/Line Manager.

Measures:

In Process measure: Quality Alerts, TAMU compliance and completion

Out process measure: On hold event, ppm

Action completion in technical standards Key element (%)

2.6.2 Analytical Equipment

All weighing scales must be calibrated before use. Weighing scale calibration must be done as per schedule.
Control:

Calibration certificates exist for all scales with calibration date and due date for next calibration- QA Leader.

Measures:

Daily weighing scale calibration checklist

3.1 Process Control Strategy Level 1 – PACKING MATERIAL**3.1.1 Material Receipt**

Materials that do not match the material receipt checklist requirements are rejected back to the warehouse.

Control tool:

Material receipt checklist- Shift QA leader

Measures:

Total rejects per Supplier/size

3.1.2 Material Usage

Materials with defects are removed from the line and a complaints form is filled with a sample of the material and provided to the Process Leader/MPD Leader. The Process Engineer/MU Owner reviews the Material utilization tracking weekly to highlight major variances and fix using the Why-why analysis tool.

Control tool:

Complaint's form-L-MPD Leader/Line Operator

MU tracking tool- Process Engineer

Measures:

Complaints per supplier

MTD Downtime due to Packing material Quality (PR loss in %)

Department MTD MU/ cents/SU

3.1 Process Control Strategy Level 1 – RAW MATERIAL (powder)**3.1.1 Material Receipt**

Powder that does not match the density and appearance requirements according to Buggy Handling SOP are rejected and sent back to MSG.

Control tool:

Buggy receipt cards-Buggy Operator

Buggy Density Station- Density Station

Measures:

Number of OOS powder buggies dumped from MSG to the Buggy floor daily

3.2 Process Control Strategy Level 1 – CHANGE-OVER, START UP & SHUT DOWN**3.2.1 Change-over**

The process engineer collects the changeover observation sheet filled by the Line Operator after every change over to analyze the individual elements time versus the target time. For repeated issues of time per element, he leads a root cause analysis to determine the reason and fix the problem according to the Why-why analysis tool.

Control tool:

Change over observation sheet-Process Engineer

Measures:

MTD Process Reliability losses due to changeover %

MTD stop 30mins after changeover

3.2.2 Startup / Shut down

The process engineer at the end of the month leads an investigation into the top losses as a result of process failures encountered during start up or shut down by doing a root cause analysis to reduce/eliminate the occurrence of such failures.

Control tool:

Proficy stops updating-Line Operator

Stops analysis-Process Leader

Measures:

MTD Startup /shut down losses due to changeover %

MTD number of Unplanned Stops/failures (per machine)

3.3 Process Control Strategy Level 1 – PRODUCT REPACK

3.3.1 Product Repack

The SAP KU leader tracks the number of repack operations done in the month to understand the reasons for the repack operation and uses root-cause analysis tools to fix any issues.

Control tool:

MU tracking tool-SAP KU leader

YY tool- SAP KU leader

Measure:

MTD Material Utilization %

3.4 Process control strategy level 1 – PROCESS/EQUIPMENT CONDITION

3.4.1 Buggy Operation control strategy

The Process Engineer checks the buggy data in the quality window if the Density for all data points is within specification and compliance to target requirements ($T \leq 0.5$, $Cr \leq 0.75$).

Process Engineer checks the number of quality incidents related to buggy floor operation and investigates the issues to identify the root cause.

Control tool:

Buggy floor quality window-Process Engineer

Measures:

Powder Density Compliance

3.4.2 Packing Operation

A change control is raised before any change is initiated in the Packing operation and all Equipment and processes in the operation must be validated before use.

Control tool:

Approved Validation master plan-Process Engineer

Change control- Process Engineer

Measures:

% Validations done on time on the Master plan

3.4.2.1 UVA 222 & Multilane

The machine is operated as per approved centerlines; RLS, CIL and maintenance activities are executed as per schedule. The Process Engineer monitors daily and weekly the operator's compliance to centerlines.

Control Tool:

CIL checklist-Machine Operator

Maintenance activity checklist-Maintenance Team

Downtime tracking-Process Engineer

Process Audit quality window -Process Engineer

UVA& ML Centerline Sheet-Machine Operator

UVA &ML troubleshooting guide-Machine Operator

Measures:

MTD Process Reliability (%)

Daily Unplanned Stops

Process Centerline Compliance

PM Scorecard

3.4.2.2 End of Line Operation

The Polywoven packing operation is done in line with packing standards, which are stated on the Test method which comprises TAMU for Polyfilm, Polywoven and Pallet.

Control:

End of Line TAMU check (Secondary packaging) –Machine Operator

Material Packing Standard-Shift QA leader

Measures:

MTD Downtime due to End of line issues (PR loss in %)

Number of Q-alerts/QI for End of line activity (undercount, wrong secondary packing (Polywoven) case usage, etc.)

3.4.3 Variable check

The weight of packed product is in line with Weight control SOP. The Process engineer verifies that the weight dosing is in control by reviewing the sample weights control chart meets target requirements ($TZ \leq 0.5$, $Cr \leq 0.75$).

Control tool:

Weight quality window - Process Engineer

Measures:

MTD Over pack (%)

MTD Under pack (%)

MTD weight compliance

3.4.4 Attribute check

The Shift QA leader records data in the TAMU quality window as per sampling plan. For any observed defects, the Process Engineer and QA leader leads an investigation to verify the root cause of the problem and institute a systemic solution.

Warehouse pickups are done weekly to verify the line quality results; observed defects from the warehouse

pickups are investigated.

Control Tool:

TAMU checklist/Quality window – Shift QA leader / QA Leader

Measures:

MTD PPM report

Warehouse Pickups

3.5 Process Control Strategy Level 1 – VARIABLE COMPLIANCE

3.5.1 Test Methods

Only approved Test methods and Packing standards are used on the line. The Process Engineer and conduct a monthly Shift QA leader ensures all technical standards on the line are up to date and functional.

Control:

No un-approved standards on the line-Process Engineer/ Shift QA leader

Measures:

Action completion in technical standards Key element (%)

3.5.2 Analytical Equipment

All Weighing scales are calibrated as per schedule.

Control:

Calibration stickers exist for all scales with calibration date and due date for next calibration- Shift QA leader/QA

Leader

Measures:

Daily Calibration checklist.

4 PROCESS CONTROL STRATEGY LEVEL 2

4.1 Process Control Strategy Level 2 – PACKING MATERIAL

The MPD leader analyses the packing material complaints from the operations and works with the suppliers in other to determine the root cause, develop and implement actions to eliminate the issues and prevent re-occurrence.

Control tool:

Pack Mat. Complaint Forms- Shift/Machine operator/MPD leader.

Measures:

Supplier Claims

4.2 Process Control Strategy Level 2 – POWDER

SAP KU leader will share monthly powder MUV and gap analysis to eliminate losses.

Control tool:

Powder MUV- SAP KU leader/Process Engineer

Measures:

Monthly MUV Report

4.3 Process Control Strategy Level 2 – CHANGE-OVER, START UP & SHUT DOWN

Process Engineer would monthly summarize the PR losses due to change over and institute a gap analysis and investigation, develop and implement actions plans to eliminate losses.

Control tool:

PR tracking in DDS sheet- Process Engineer

Measures:

Monthly PR

4.4 Process Control Strategy Level 2 – PRODUCT REPACK

The SAP KU leader tracks the number of repack operations done in the month to understand the reasons for the repack operation. The QA tracks the on-hold event for repack and the right quality measures are followed. The Process Engineer evaluates the losses due to this repack operation by investigating the issues, developing and implementing actions plans to fix the problem.

Control tool:

MU tracking tool - SAP KU leader / Process Engineer.

Measures:

Material Utilization %

4.5 Process control strategy level 2 – PROCESS/EQUIPMENT CONDITION

The Process Engineer reviews the unplanned stops/MTBF for the operation at the end of the month to identify the key issues, lead investigation, develop and implement action/improvement plans.

The Reliability Manager and TSG team analyzes the breakdowns, investigate to determine the root cause, develop and implement action plans.

The QA leader verifies the Variable and Attribute parameter compliance at by carrying out Trade surveys to identify key issues; lead investigations with the Process Engineer; develop and implement action/improvement plans.

Consumer complaints are fed back to the Process Engineer and the key element 17 – Consumer Complaints and response who leads investigations.

Control:

TAMU Quality window –QA Leader

Weight Quality window-QA Leader

Monthly Breakdowns Analysis-Process Leader

Monthly Unplanned Stops -Line Manager

Measures:

Monthly Process Reliability

Monthly Unplanned Stops

PM Scorecard

SQM/Trade survey

Consumer Complaints

4.6 Process Control Strategy Level 2 – VARIABLE COMPLIANCE

4.6.1 Test Methods

Quarterly review of Test methods and Packaging standards

Control:

Standards approved on CSS-Process Engineer/ QA Leader/MPD Leader

Measures:

Monthly PPM report

4.6.2 Analytical Equipment

All Weigh scales are calibrated by an approved contractor every year.

Control:

Calibration certificates exist for all scales with calibration date and due date for next calibration-QA Leader.
Measures:

NA

REASON FOR UPDATE: VERSION 0: New SOP

End of Procedure

SOP RELATED ATTACHMENTS

Attachment 1 - Training and Qualification Sheet
Attachment 2 – Model Answer
Attachment 3 – PSG Equipment List
Attachment 4 – PSG control Loop
Attachment 5 – PCS Step up Card