	UGEE CHEMICALS Plant General SOP	SOP Standard Operating Procedure

QUALITY ALERTS & INCIDENT REPORTING SYSTEM

SOP #: UCL/IBDSITE/CD/Q/20.0	Issuance Date:	As at Last Signature	
	Revision Date:	Maximum 2 years after effective date	
	Effective Date:	20 Working days from the issuance date	Page 1 of 8

PURPOSE

- To establish a uniform method for identifying classifying, reporting and investigating Quality failures (Q Alerts and Quality Incidents), The procedure helps to identify root cause(s) of the quality system failure, develop systemic corrective action and preventive actions, also to analyzing aggregate quality system failure data following QIE methodology to eliminate them.

SCOPE

- This procedure applies to Ibadan plant.

RESPONSIBILITIES

- **Site QA Leader** ensures site follows this procedure. He /She also ensures that all QIs are reported to the plant manager and appropriate clients Company's Quality Assurance representative within 24 hrs of discovery. Archives the investigation documents used for QIE on one drive and the hardcopy in investigation folder.
- **Clients QA** the client's QA reports the QIs on their QMS system and classify as appropriate.
  He shares top quality failures on monthly basis and ensures Q-alerts and QIs are appropriately investigated, immediate corrective action plans implemented, root causes identified, systemic action plans developed and implemented to prevent recurrence and planned Improvement are realized. He /She is responsible for tracking number of Qis in the plant
  Line/Department managers will report all QIs/Q-alerts to Quality Assurance Manager/Plant QI system owner with 12 hours of discovery. He/She will also investigate each Q-alert and QI in his or her area of responsibility. He /She will lead re-application of systemic action plans across production lines. He will calculate the cost of the QI. He drives and implement QIE in his area. He will also share learnings from QI to plant leadership during monthly Quality update in site Leadership meeting.
  Team Leaders will ensure his team reports Quality alerts, lead investigation of Quality alerts and Quality Incidents in his/her team and reports all Quality incident to the department leader.

POTENTIAL RISKS

Not Applicable

SOP OWNER	QA APPROVAL	HS&E APPROVAL	AUTHORISATION
----------	----------NA----------	----------NA----------	----------
Adio Sakiru			Site QA: Alawode Olujide
Date: 09/02/2021	Date:	Date:	Date: 09/02/2021

PPE REQUIRED

Not Applicable

PROCEDURE

Quality Incident System:

1. In the event of a quality failure, the line is stopped, and all products made put on hold.
2. If determination is that the failure is appropriately classified as an alert, this SOP will be followed.
3. For MSG operations, any quality system failure that escapes to PSG and goes beyond the packing conveyor will be classified as QI i.e. If the product has been loaded on machine and it has been packed and stacked on pallet.

Quality Alert System

4 Once a Quality Alert is identified, the person and/or shift leader will fill in the data electronically on Q-alert platform or in Quality Alert Report Sheet (See attachment 3). The attachment 3 is also the back up for Q-alert platform.

5 On daily basis, within the team meeting, the QA leader will share with the team the alert number, causes, category…etc) and immediate action must be provided while basic actions will be determined once the analysis is completed.

6 Department QA Leaders tracks all the alerts using the alert tracking sheet.

7 The QA Leader then shares the tracked alert with the department and site leadership monthly on or before 4th Working day of the new month.

8 Top three alerts will be analyzed monthly using either QIE, UPS, WPI and OPM- This is driven by the respective department leaders

9 All investigations and action plans must comply with CAPA and flow to department consolidated action sheet.

10. All investigation documents used for QIE must be archived on "One drive".

Definitions

An Alert is a quality system failure that was caught early in the system, prevented a major loss and does not meet the definition of a QI i.e., it is contained within the part of the operation (i.e. receiving/Making/Packing) in which it occurred before release to the next stage.

A Quality Incident (QI) – is a P&G quality system failure that results in losses, or a quality system failure that risks compromising the quality and integrity of the Company's products or reputation. A QI is also defined by the passing of a review/approval quality gate with a known quality system error/failure.

Repeat Quality Incident: A repeat quality incident is defined when more than one quality incident meets all the following criteria

1 Same site

2 Same system that failed
3 Same root cause
4 Occurred within 12-month Period

Note "same site" is defined by the site number. Some physical sites have two site numbers, If the intent is to manage the physical site as one site, then consider the" same site" criteria has been met

QIE: Quality Incident Elimination

CaPA: Corrective action, Preventive action

Quality system failure classifications include: Contamination, Release Errors, Inadvertent Shipments, and Transportation or Customer Delivery Damage

Potential sources of QIs may include, but are not limited to, consumer or customer complaint investigations, internal audit observations, citations or written notifications from regulatory bodies or other outside agencies

End of Procedure

SOP RELATED ATTACHMENTS

Attachment 1 – QI SOP Training and Qualification
Attachment 2 – QI Model Answers
Attachment 3 – Q alert reporting Form

Quality Alert Report Form

Basic Information

Date Discovered: (Month/Date/Year)

Person Reporting: (name of person)

Brief Description of Event

(Clearly describe object and the object defect, e.g. defective roller)

Shift Discovered | Time Discovered

Team Discovered | What unit of equipment failed

Product Involved | Machine #

Details of (Made/Packed) Product involved:

Product Name/Code Date

Product Quantity Involved (Batches,Cases,MSU)

Made/Packed Product Affected | Made/Packed Product Location

Immediate Cause:

Action (Immediate Actions taken and/or suggested action plans)

Basic Cause (Circle as appropriate)

1.Human Element

1.1 Person is not trained / Qualified
1.2 Person chose not to follow the method
1.3 Person chose another method without showing reasons

2. The method SOP

2.1 No method
2.2 The method is hard & can't be understood
2.3 The method is not correct
2.4 The method is hard to follow

3. The equipment / the process

3.1 Equipment failure
3.2 Equipment process out of center line
3.3 Inadequate equipment change control/validation

4. The raw materials & the packaging materials

4.1 Supplier not capable of delivering specified material
4.2 Material specification limits incorrectly set
4.3 Supplier related material failuree-human error
4.4 Supplier related material failuree-method causes
4.5 Supplier related material failuree-equipment causes

BASIC ACTION(s):

Other Details:

Product Status:*

Total Cost Involved:

(*not applicable if no made or packed product involved)

Comments.....

SOP OWNER	QA APPROVAL	HS&E APPROVAL	AUTHORISATION
Adio Sakiru	----------NA----------	----------NA----------	Site QA: Alawode Olujide
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