Standard Operating Procedure
Title: Product Complaint Procedure

Department	Quality Management		Document no	QMS-055	
Prepared by:		Date:		Supersedes:	
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Approved by:		Date:		Review Date:	

Document Owner
Quality Assurance Manager

Affected Parties
All Manufacturing Employees

Purpose
This procedure descries the process to ensure that product manufacture by the site are documented, evaluated, monitored, reported, and trended in accordance with regulatory and corporate requirements.

Scope
The scope of this procedure covers receipt, logging, evaluation, investigation and reporting of all complaints received by the site Customer Complaint and Quality Assurance Departments.

Definition

A Complaint	A complaint is any expression of dissatisfaction with a product or service marketed.
Complainant	A person or organisation making a complaint.
Customer	The person or institution making the complaint
Critical Complaint	A complaint that strongly indicates the purity, identity, safety or efficacy of a product may have been compromised and has the potential to cause a life threatening or serious health situation.
Serious Complaint	A complaint that indicates the purity, identity, safety or efficacy of a product may have been compromised, but does not present as a life threatening or serious health risk.
Standard Complaint	A complaint that is neither critical nor serious.
Justified Complaint	A complaint where the investigation has shown the complaint to be valid and that it occurred under company control.
Non-Justified Complaint	A complaint where the investigation has shown no valid reason for the complaint.
DR	Deviation Report System
MI Sheet	Manufacturing Instruction Sheet
BPN	Batch Production Number

Related Documents

Form-465	Complaints Details form
Form-490	Laboratory Testing Form For Customer Complaint Enquiry
Form-405	Complaint Investigation Report
Form-570	Process Data Collection Form
LAB-045	Retention Samples - Laboratory

- If the customer has returned multiple samples of the same batch number and clearly indicated that all are for the same issue, then these are be logged as one complaint.

1.6 The package containing the complaint form (**Form-465**) and sample is send to the Quality Assurance where the details are checked and an evaluation of the product can be made.

2. Evaluation of Complaints

After getting the Complaint Details Form and the samples, the QA Staff has to initiate the following things:

- The initial evaluation of complaints
- Create a QA complaints spreadsheet and enter details of the complaint in the file
- Determine the investigation plan and send the complaint samples to either in Production, Laboratory or other contract manufacturers as appropriate.
- Ensure the complaint investigation and documentation is completed within the time frames.
- The Area Managers or Laboratory Manager should be responsible for giving the complaint sample to appropriate staff for investigation with necessary directions (i.e. Finished Product specification or control method) and to finish within the specified time. They have to ensure any corrective action is taken to rectify problems identified.

2.1. Initial Evaluation

To be read in conjunction with Appendix 1.

2.1.1. QA Staff has to read all information available in the Complaint Details Form concerning the particular complaint. Ensure that all information entered in the form is correct, and make necessary changes if it is not.

2.1.2. Check batch number details for all parts of the product returned. The product and the outer packaging may have been interchanged. If the batch numbers are different, then use the batch number of the actual product or unit. Enter details into QA Complaint spreadsheet like Expiry Date, product Code and Box Number for storage of sample after evaluation.

2.1.3. Enter information relating to the quantity and condition of product received, e.g. number of units, containers are whether full, empty, used, opened, sealed or damaged,. (This is very important, especially if tampering with the product is suspected.)

2.1.4. Label the returned product securely with the Complaint Reference Number quoted from the Complaint form (**Form-465**) and the Storage Box Number on all sections of the complaint sample that are able to be separated e.g. Outer packaging.

2.1.5. For suspect counterfeit or tampering complaints the chain of custody needs to be maintained. Refer to section 7 of this SOP.

2.1.6. Determine if the complaint is critical, serious or standard. If the complaint is critical in nature inform the QA Manager, or delegate. Complaints should be worked on in order of severity, (i.e. critical complaints get highest priority).

2.1.7. Determine the Site of manufacture.

- If the product has been in-house manufactured, go to section 2.2.
- If the product has been imported or contract manufactured, go to section 2.3.

2.2. Complaints for In-house Manufactured Goods

To be read in conjunction with Appendix 2.

2.2.1. Review the old complaints in the QA Complaint Spreadsheet to determine whether a similar complaint has been received.

5.2.2. Sample is to be placed in a sealed, preferably transparent plastic envelope that is securely sealed.

5.2.3. If the envelope has to be opened, then the person, who is at that time in possession of the envelope, shall record in the notebook or forms, the details as to why it was opened, the time and date, who was present and when the envelope was resealed.

5.3. QA management will inform the supply chain manager that a suspect sample has been received at site and initiates the investigation which includes the following steps:

5.3.1. Determines the site at which sample should be investigated and securely forwards sample to manufacturing site with the Chain of Custody form if appropriate.

5.3.2. For samples investigated in house, the following are suggestions for the examination of suspect samples:

5.3.2.1. **Examination of the Pack**

1. Visually check pack against “market pack” and for pack completeness.
2. Dimensional characteristics.
3. Artwork comparison which includes the following:
   - Wrong or extra wording
   - Stickering / Overstickering / Hand Stamps
   - Colour variation
   - Company logo
   - Font differences.
4. On-line Data which includes the following:
   - Confirm batch/lot number
   - Confirm batch/lot number/expiry date match
   - Differences in application of the variable data, (e.g. Printing/embossing)
   - Standards of presentation of variable data.

5.3.2.2. **Product Examination**

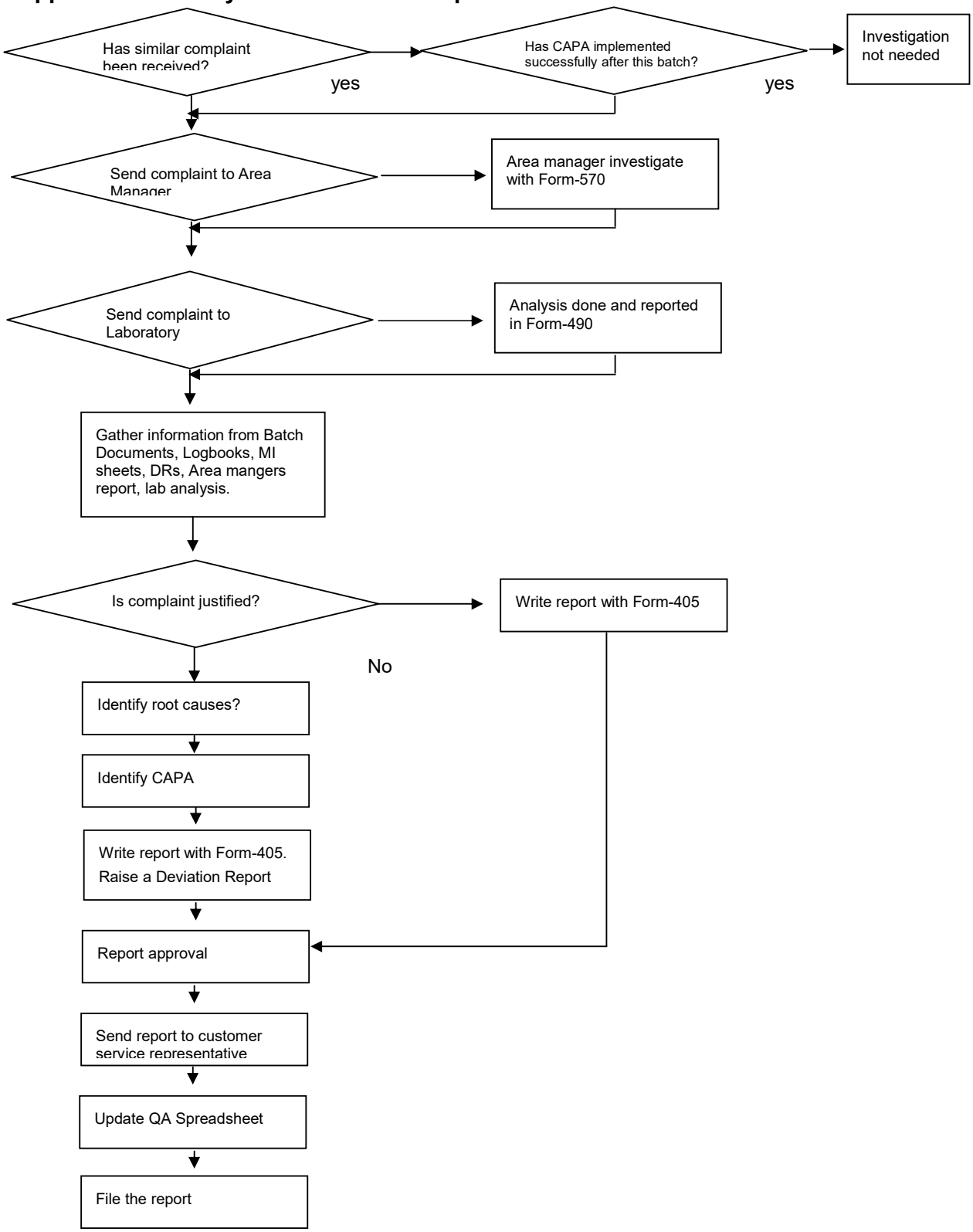
- Non-Destructive Testing
- Dimensional characteristics
- Appearance, intagliation, colour
- Destructive Testing (i.e. Assay)

6. Reply to complaints

6.1. It is the responsibility of the Customer Service Representative or Manager to write a response, have it reviewed and signed off by Marketing and Customer Service Manager and send to the customer within four weeks of receiving a complaint.

7. Appendix 1: Product Complaint Initial Evaluation Flowchart

8. Appendix 2: Locally Manufactured Complaints Flowchart



Laboratory Testing Form For Customer Complaint Enquiry

(Ref. SOP QMS-055)

Complaint Ref. No							
Batch Number (BPN)							
Specification Ref. No							
Test Description.	**Specification**	**Returned Sample**	**Retention Sample**	**Analysis Method**	**Analyst**	**Date**	**Book /Page Reference**
Results Checked by							

Process Data Collection Form

(Ref. SOP QMS-055)

Consultation with technician/Process Engineer.

- Consult the Process Technician / Process Engineer. Describe the complaint and show the complaint picture. Use the space below to record the answers to the following information.

Q1. Have they seen this problem before? If so, what did they do to rectify this?
Q2. Do they have any ideas as to what the problem was caused by?
Q3. Do they have any ideas as to how to prevent this problem from occurring again? (Process improvements)

Collate all of the above information and determine a causality of the defective product. Describe below:

PART 2. CURRENT PROCESS CONTROLS

Current Practices.

- Describe the current process controls that would normally prevent this defective product from reaching the customer.

- Describe how this control could be by-passed, thus allowing the defective product to reach the customer?

Process Improvements.

- What are possible process improvements to prevent this problem from reoccurring?

