

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 describes the process to ensure that product manufacture by Sydco 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 Sydco 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

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- If the customer has returned multiple samples of the same batch number, but clearly indicates that there is more than one complaint, then these issues must be logged separately.
 - 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](#).

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- 2.3.1. The process for Imported or Contract Manufactured complaints is very similar to locally manufactured complaints. The difference is that the responsibility for investigation is for the contract manufacturer.
- 2.3.2. For Investigation by Contract Manufacturer, forward sample with covering letter detailing the complaint and results of initial evaluation to designated contact.
- 2.3.3. Keep track of complaints with the contract manufacturer so that they will be analysed and reported within the specified time frames.

3. Storage of Samples

The QA Staff is responsible for the storage of samples using the following process:

- 3.1. Disposal of samples takes place as set out in **SOP LAB-045**. Samples are to be kept for one (1) year past their expiry date. Boxes are kept in designated Complaint Storage area in the retention Sample Room.
- 3.2. The system in place allows for samples to be stored in numbered boxes that can be easily discarded at the end of the storage period.
- 3.3. The boxes are numbered and clearly labelled "Complaints, Box Number ---, "To be discarded in December XXXX" (the appropriate year for sample disposal). Details and allocation of Box numbers are recorded in the table QA Complaint Spreadsheet:

4. Trending of Product Complaints

- 4.1. The Quality Assurance staff reviews the data entered into an Excel **Spreadsheet for Customer Complaint**, periodically to determine if there are any unfavourable trends in the Complaints Data.
- 4.2. The data is analysed based on the following criteria:
 - 4.2.1. Process Line (for In-house manufactured goods)
 - 4.2.2. Product Code
 - 4.2.3. Date of Manufacture
- 4.3. The data will be sent to management for review and copy of the data will be held in QA files under "Quarterly Complaints Trend Review".
- 4.4. Any unfavourable trends will be discussed in the Quality Meeting with the view to generate Continuous Improvement Plans and Preventive Action Plans to reduce the level of complaints received for the issue identified.

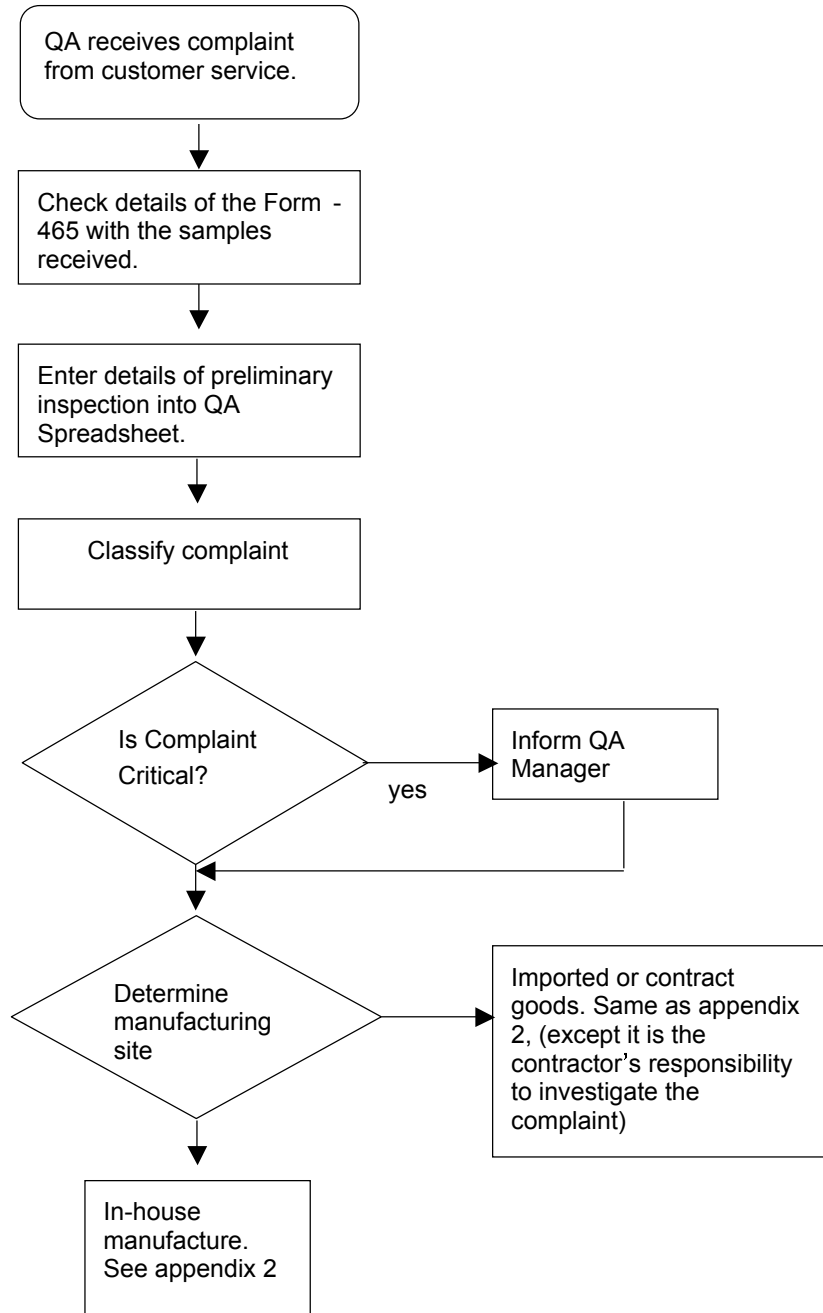
5. Handling of Suspect Counterfeit Samples and Product Diversions

- 5.1. **A sample will be suspect if there is reason to believe that :**
 - A counterfeit product and/or pack
 - Product that has been tampered with
 - Product that has been diverted from the normal supply chain.
- 5.2. A written and documented record (Chain of Custody) of the history and movements of the suspect sample to support any legal prosecutions has to be initiated and maintained with sample by the designated QA Staff if a suspect sample is received and should include the following information:

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7. Appendix 1: Product Complaint Initial Evaluation Flowchart



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9. Summary of Changes

Version #	Revision History
QMS-055	New

End of Procedure

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							

Complaint Investigation Report

(Ref. SOP QMS-055)

Conclusion

Provide a brief summary of the complaint, its cause(s) and preventive actions.

Approval

Authorisation		Signature	Date
Prepared by:			
Checked by:			
Approved 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?
