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Review Article

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Standard Operating Procedures for Feedback and Complaints in Healthcare Organizations

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Abstract

The purpose [1] of this policy is to ensure the existence and accessibility of a procedure through which patients, stakeholders, and employees can communicate feedback or complaints regarding an organization`s services, functions, or operations. We also describe how to respond to a complaint through a systematic approach for immediate recall, investigation, and remedial measures. Such policies enable organizations to benefit from feedback and complaints by ensuring they are recorded, considered, resolved, and monitored. Organizations should ensure that patients, stakeholders, and employees are aware of the content of this policy and relevant procedures and that each person making a complaint receives support that reflects their individual, cultural and linguistic needs to aid them in understanding and participating in the complaint's management process. This procedure applies to any written or oral expression of dissatisfaction and all complaints received by organizations concerning business practices and patient support programs (Patient support programs, where applicable) [2].

Key words: *SOPs; Feedback; Complaints; Healthcare*

Abbreviations: NA

Introduction

Healthcare organizations are responsible for allowing the FDA, Marketing Authorization Holder, and local health authority to review complaint records and/or the "Adverse Event Report Form" related to all regulated products (refer to pharmacovigilance and Standard Operating Procedures for Adverse Event reporting Policy). The organization must ensure that patients, stakeholders, and employees are informed of the existence and accessibility of the feedback and complaints policy and procedure at the commencement of services. Complaints procedure should be maintained to ensure that all feedback and complaints are responded to in a respectful, timely, confidential, and impartial fashion. All suggestions for improvement, feedback and complaints are recorded, considered, and retained for process improvement purposes. The organization will encourage patients, stakeholders who have a service or behavior related complaint to express the issue through the complaint's procedure. The organization will ensure that the complainant is informed of his or her right to have a support person or advocate present to assist or represent them during the complaint procedure. The organization will ensure that all responses and decisions related to complaints will be made with sensitivity to the age,

culture, language, religion, gender and sexuality of the complainant, with consideration made for older people, people with a disability, their caregivers, and advocates. The organization will ensure that any complaint is free of repercussions for the complainant. Management will take all steps necessary to ensure that no victimization is directed towards anyone who makes a complaint. The organization recognizes the right of individuals to approach an external agency if the complaints procedure has not resolved the issue to their satisfaction.

Procedures

Policy Principles [3]

Types of Complaints

Service-Related complaints express dissatisfaction by customers, whether patients or stakeholders, during the running of a patient support program or use of a service provided by the organization [4].

Examples include:

- A programmed service that has not been provided to the predetermined standard (timeline, quality, and quantity).
- A requested service that should have been provided but has not been provided to the predetermined standard (timeline, quality, and quantity).
- The use of medicine (Procedural complaint).

There are several types of Medicine-Related complaints that apply to medical products produced by an organization [5].

- Quality complaints originate at the consumer level and regard a concern with physical, chemical, and/or biological properties or the condition of labeling and/or packaging of the product.
- Adverse reaction complaints: Due to allergic reactions of any other untoward reaction, fatal reaction, or near fatal reaction.
- Complaints about a lack of efficacy or clinical response.

Complaints Regarding Statutory Matters [6] occur in organization's whose activities are governed by country or global legislations, the organization is unable to alter its decision-making processes and is guided by the requirements of the legislation. Such procedure applies when the organization has adopted local laws that operate in conjunction with local country legislation. When the organization's officers commence proceedings, including legal action and issuing infringement notices, and a member of the community wishes to have the decision reviewed, a request for review will be received in writing. Such matters will be handled by the responsible officer as a service request.

Risk Management Issues [7] include when a complainant informs the organization that a claim may be lodged for personal injury or property damage, the Risk Management Officer shall be advised of the complaint and the responsible officer will liaise with the Risk Management Officer in handling the complaint.

Complaints about Staff Behavior [8] will be handled sensitively and confidentially. All complaints regarding the professional behavior of officers will be made in writing and include the detail necessary to allow investigation of the complaint. These complaints will be handled through the complaints handling process with the relevant manager initially investigating and resolving the complaint. The director will become involved if the complaint cannot be resolved. All aspects of the complaint, discussions, and resolutions shall be accurately recorded and may form the basis for disciplinary action. Staff will be given the opportunity to nominate their own independent, impartial agent should they consider the complaint warrants such participation. Where a complaint is about discrimination, the Organizational/Business Development Manager shall manage the investigation and act as an independent/impartial agent.

Results

Responsibility [9]

Employees are responsible for reporting all customer complaints to Customer Service or the local Customer Action Report (CAR) Coordinator.

The Customer Service or local Customer Action Coordinator is responsible for:

- Reviewing the Customer Action Report Form and determining the need for further customer service or technical support after consultation with appropriate experts.
- Assigning a Customer Action Report number to the report.
- Maintaining copies of all local Customer Action Report documentation.
- Ensuring follow-up customer service actions are completed and forwarding the Customer Action Report form to the Quality Assurance/Quality Control Manager.

The Quality Assurance/Quality Control Manager is responsible for:

- Determining the need for a complaint investigation and assigning the investigation to the relevant personnel.
- Confirming the presence of a product/service problem.
- In the case of quality, adverse event reaction, or medically related complaints, Quality Control is responsible for determining whether a complaint requires review by Marketing Authorization Holder.
- Tracking complaint investigation, corrective action, and verifying resolution in a timely fashion. This includes preparing periodic Customer Action Report status and tracking reports.

Assigned complaint investigators are responsible for completing and documenting the investigation in a timely manner.

Document Control personnel are responsible for retaining all original complaint records and reports.

Discussion

Source of Complaints [10]

The source of a complaint can be either written or verbal and received over the telephone or in person by any employee or representative of the organization. Complaints also include issues observed during service, in a Quality Assurance/Quality Control released product during internal use, or issues with customer training.

Receipt of Complaint [11]

Complaints can be lodged through different channels and at any level. The complaint will be first lodged with the employee/officer related to the source of the problem. The officer receiving the complaint will then escalate the matter to the appropriate level.

Verbal complaints include both face to face discussions and complaints received over the telephone. The employee receiving the complaint will [12]:

- Introduce themselves, determine the details of the complaint and record the complaint in the customer request system (including necessary information).
- Confirm the details received with the complainant.
- Explain to the complainant the available courses of action.
- Commit to positive action immediately and seek to resolve the complaint (if possible).
- Determine whether the person making the complaint is satisfied with the proposed course of action, if not, suggest an alternative.
- Follow up and monitor the outcome to confirm that the person is satisfied and has received appropriate feedback.
- Should the nature or severity of a verbal complaint appear major, the officer will request that the complaint be put in writing to reduce the possibility of a misunderstanding.

Written complaints are registered by Central Records and delegated to the relevant manager or director. The officer receiving the complaint will [13]:

- Acknowledge the complaint in writing within two working days of its reception.
- Where written complaints are resolved quickly, a letter of reply will replace the letter of acknowledgment.
- Where written complaints raise issues, which require follow up or investigation by the officer, the letter of acknowledgment will also give a tentative response date and outline the process for resolving the complaint.
- Record the complaint in the customer request system.
- Follow up and monitor the outcome to confirm that the person is satisfied and has received appropriate feedback.

In the letter of reply the officer will [14]:

- Outline the complaint received.
- Explain the courses of action available.
- Commit to positive action immediately.
- Ask the complainant to contact the officer if they are not satisfied with the proposed course of action.

Conclusion

Responsibility for Responding to Complaints [13]

Contracted services

In-house and external contract complaints will be delegated to the contract manager/ Client Engagement Manager to resolve with the contractor. It is the responsibility of the contract manager/ Client Engagement Manager to receive and handle service complaints.

Non-contracted services

These complaints will be assigned to the relevant manager for investigation and resolution.

Escalation of Complaints to Mediation [15]

Where a dispute remains unresolved, a senior member of staff shall be nominated to mediate. This officer will investigate the unresolved complaint with a view to resolving the matter. If mediation

is required, the related director will invite a director from another area to act as a mediator.

Mediation [16]

The mediation process will not be used to review formal decisions, but rather to check that complaints have been handled correctly and that the decisions made reflect the organizations` policies. The mediator will:

- Act independently.
- Consult with the director to confirm that the complaint has been acknowledged within two working days of reception and the complainant has been advised of the complaint handling process.
- Ask the responsible manager to provide all information associated with the complaint and provide any additional background information.
- Review all material before speaking to the complainant and officers involved.
- Forward a written recommendation to the director and/or the CEO.
- Notify the complainant of the decision in writing.
- Place copies of all notes, correspondence, and other relevant materials on a central file.
- If the complaint has not been resolved by the director or the mediation process, the complainant can seek to discuss matters with the CEO.

Right of Appeal [17]

If a member of the community is dissatisfied with the senior officers' decision, they have the right to involve the court of law.

Reporting [18]

A report will be made annually to the Full Management Team detailing the number of complaints, the service the complaint relates to, and the level at which the complaint was resolved. This information can then be analyzed to understand what training or improvements need to be made.

Initiation of a Complaint: "Customer Action Report Form Process" [19]

Good documentation practices will be followed in documenting activities relating to complaints. This includes completing all information spaces on the forms with either the information, "N/A" if not applicable, or "Unknown" if efforts to obtain the missing information fails.

If a customer contact (verbal or written) meets the definition of a complaint as described before, the representative will initiate a Customer Action Report Form within 7 days. The Customer/Technical Service Representative and/or the local Customer Action Report Coordinator will work with an organization representative to attempt to resolve the problem over the phone. A summary of the initial actions or responses to the customer is recorded on the Customer Action Report Form. The organization's representative then completes the Customer Action report form and forwards the form to Customer Service or the local Customer Action Report Coordinator.

Customer Service or the local Customer Action Report Coordinator review [20]

Customer Service or the local Customer Action Report Coordinator will review the report and determine if additional action or customer follow-up is required and assign follow-up to a representative.

Additional customer follow-up may include dispatching of a Field Support Personnel to the customer site, the replacement of defective products, or return of defective products

Customer Service or the local Customer Action Report Coordinator will investigate local service complaints. Before forwarding the form to the Quality Assurance Department.

All customer service actions will be documented and attached to the form.

Customer Service or the local Customer Action Report Coordinator will sign and date the Customer. Action Report Evaluation Form and forward the original form to the Quality Assurance Department.

Initial Quality Assurance/Quality Control Manager review [21]: Determination of Need for Investigation

All Customer Action Reports are sent to Quality Assurance/Quality Control Manager, or delegate, for review. A delegate must have a thorough knowledge of the product, to make an informed, reasonable decision as to the severity and significance of the complaint.

The Quality Assurance/Quality Control Manager, or delegate, determines the need for additional investigation to confirm the existence of the problem. If no additional investigation is required, a record is made on the Customer Action Report of the rationale used to arrive at this decision.

If an investigation is required, an investigator is assigned responsibility for the investigation.

The Quality Assurance/Quality Control Manager has the option of designating an investigation plan, which may include the following:

Testing of retention sample or product returned from the customer. Review of the development, production and/or stability records. Review of the customer data.

Quality Assurance periodically follows-up to confirm that investigations are carried out in a timely manner, including the preparation of periodic Customer Action Report status reports.

Customer Action Report Investigation and Documentation [22]

Upon receipt of the investigation request and Customer Action Report package, the investigator will perform the investigation directed by the Quality Assurance/Quality Control Manager.

If the investigator requires others to assist with the investigation, the investigator will notify Quality Assurance. Quality Assurance will add their names in the investigator's column of the Customer Action Report log.

The records of the investigation are documented and the assigned investigator signs. And dates the Investigation Report form and sends the form and copies of all documentation to Quality Assurance.

All investigations must be documented, regardless of outcome

Quality Assurance Customer Action Report System Administration [23]

Following completion of the investigation and Quality Assurance/Quality Control Manager's review, Quality Assurance will assign a complaint type for trending purposes. Complaint types and examples are listed in the following table:

Complaint Types [24]

Complaint Type	Examples
1 - product problem	Cloudy, contaminated, or leaking. absence of or incorrect labeling
2 - device problem	leaking column broken or incorrectly assembled part incorrect labeling
3 - hardware problem	Mechanical failure of instrument or computer. broken part
4 - software problem	data mismanagement inadequate control of process software bug/ virus
5 - packaging problem	- product damaged in transit
6 - labeling / procedural Problem	Error, omission, or contradicting information in labels, insert, manuals, or field service bulletins. difficulty in understanding instructional insert difficulty in following instructional insert
7 - service problem	late delivery shipment of wrong product shipment of incorrect quantities untimely response to customer inquiry
8 – other	- Self explanatory
9 - processing problem	- A problem related to patient sample such as low yield or purity and no operator error is indicated.
10 - Operator Error	- Operator did not follow manual, instructions, insert, or protocol.

Applicable Materials

References and Applicable Documents [25]

Company Quality Manual for references to applicable regulatory requirements

Customer Action Report Log

Quality Improvement Project Monitoring System

Materials and equipment [26]

Customer Action Report File Storage Cabinets

Documentation and requirements [27]

Customer Action Report Form

Customer Action Report Investigation Form

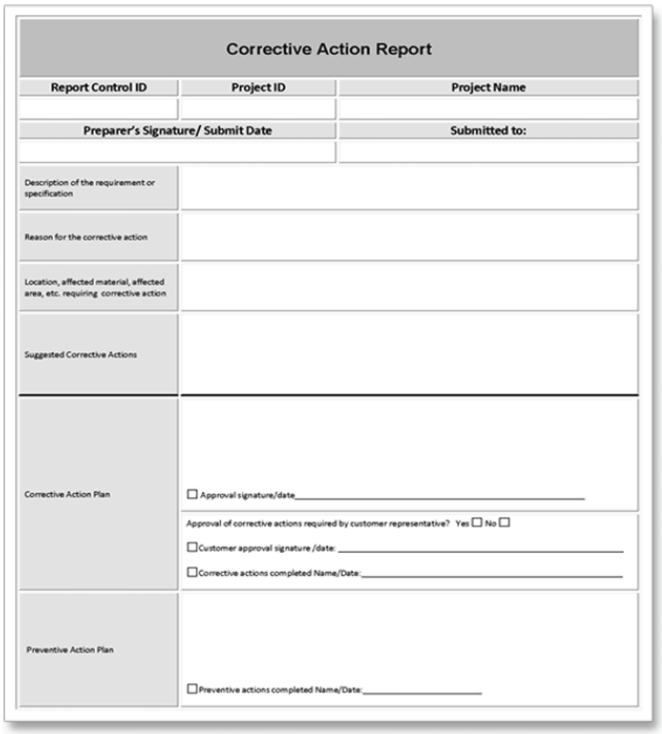
Customer Action Report (CAR) Log

Quarterly and Annual Reports on Customer Complaints

Appendices

Customer Service Action Form [28]	
Customer	Time & Date
	Originator
Telephone	Department
	Telephone
Situation requiring action	

ROUTING	
	Department
Time received	
Action taken	
Recommended next steps	
	Department
Time received	
Action taken	
Recommended next steps	
To (last)	



Corrective Action Report

Report Control ID	Project ID	Project Name
Preparer's Signature/ Submit Date		**Submitted to:**

Description of the requirement or specification	
Reason for the corrective action	
Location, affected material, affected area, etc. requiring corrective action	
Suggested Corrective Actions	
Corrective Action Plan	☐ Approval signature/date_____ Approval of corrective actions required by customer representative? Yes ☐ No ☐ ☐ Customer approval signature /date: _____ ☐ Corrective actions completed Name/Date:_____
Preventive Action Plan	☐ Preventive actions completed Name/Date:_____

	Corrective Action Report [29]	C.A.R. # Cust. Complaint #

(If Space Is Limited Use an Additional Sheet of Paper and Staple It to This Corrective Action)

1	Type: Customer Supplier Internal	Customer/Supplier:
	Part/Material #:	External Contact Name
	Quantity:	External Contact Phone:
	Initiated By:	Forward To: (for step 2)
	Initiation Date:	Due Date: Pending Due Date:
	Respond to Customer? Yes ☐ No ☐ By Date: Plant Visit Required? Yes No ☐ ☐	
	Describe the Problem:	Can the problem affect other products or processes? Is it a systemic problem that can re-occur? Responses are required by Team Champion! See Steering Committee for action
2	Team Champion: (Team Roster & Tracking Sheet Required)	Position/Group & Phone:
3	What Did You Do to Contain the Problem?	If the problem affects other Product/Process or is systemic, how were they contained?
4	Root Cause (s): Ask Why 5 Times. Personnel Failure Not Acceptable!	
5	What Actions Corrected the Root Cause? List actual actions taken, not actions that will be taken in the future! If additional time is required see Q.A. to place C/A in pending status.	
6	List Data That Verifies Corrective Action:	Was FMEA Revise? Yes No (required only when C/A is for product or process)
7	Department Manager: Accept Reject Signature: Date: Quality Assurance Supervisor/Analyst: Accept ☐ Reject ☐ Signature: Date: Quality Assurance Manager: Accept ☐ Reject ☐ Signature: Date:	
8	Congratulate Team!	Note: Quality Assurance Manager returns C/A to Q.A. Analyst for re-issue or close C/A.

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