



Company Policy on Complaints

Rev C

Date: 25th July 2019

Approved: KW Saxon

It is the policy of Deva medical to deal with complaints in a manner which is fair, impartial and designed to resolve issues in an efficient which will improve the operations of the company.

The company is committed to fully investigating and resolving complaints relating to its accredited and other services. Actions resulting from complaints are managed as corrective actions. The customer is notified of the outcomes of these actions unless they request otherwise.

If verbal complaints are made a written record is also made in the Company Complaints Log, staff will also request that written correspondence is sent by the customer to the Quality Manager, who will confirm receipt of the complaint to the complainant.

The company considers the quality of its work a primary objective, so any deviations identified are investigated immediately. The investigation will include confirming the work is nonconforming, then identifying the cause and raising any corrective actions to prevent reoccurrence. The complainant will be kept informed as to the progress of the investigation. Any other work identified as being nonconforming as a consequence will be recalled and the customers informed.

Corrective Action Policy

The Quality Manager will decide who is to implement each corrective action identified. Each instance of nonconforming work or problem will have a root cause analysis performed and appropriate corrective actions raised to prevent reoccurrence.

Purpose of the process

The aim of this procedure is to manage and progress complaints, audit non-conformities, non-conforming work, improvement suggestions, corrective and preventive actions, So that problems are corrected as soon as practicable after they arise, and ensuring that their recurrence is minimised.

As complaints may also be made internally, there are several inputs to the complaint process:

- complaints,
- audit non conformities,
- faulty product, software or parts,
- continuous improvement suggestions,
- management review actions
- staff identified problems

The outputs of the process may include, but are not restricted to:

- resolved complaints,
- completed corrective and preventive actions,
- implement continuous improvement suggestions

The records of any complaints are kept for 7 years, and are identified by reference numbers. These records are held by the Quality Manager.

Each action records contains

- Reference number
- Named actionee
- Target completion date
- A description of the action,
- Root cause explanation where appropriate
- The tracking of the action progress
- A reference back to what initiated this action (audit/ complaint/ review meeting etc.)
- Evidence of the action being implemented
- Closure of the action by the Quality Manager.



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Definitions

- **Complaint** - A complaint is where someone outside the laboratory and its staff has verbally or in writing complained to the Technical Manager or the Quality Manager regarding any aspect of its activities. Engineers and technicians are to encourage customers to make verbal complaints by putting them in writing to the Technical Manager. It is processed and recorded as described below.
- **Improvement** - Improvement opportunities that the Technical Manager has approved will be logged as preventive actions and will be tracked as described in this procedure
- **Non-Conforming Work (NCW)** - Where laboratory work is found to be defective it will be removed from the normal working areas and quarantined in a special location or in a file that has controlled access. This prevents any further work being performed and can only be released by the Quality Manager. Once the Technical Manager has evaluated the significances of the NCW he will decide what rectification and corrective actions should be taken, which may include withholding certificates, notifying the customer, reworking calibrations or other appropriate action or changing procedures or methods to prevent reoccurrence.
- **Rectification Action** - Rectification actions are for re-testing, recalibrating, rewriting reports or returning equipment to supplier for testing where it was found to be defective.
- **Corrective Actions** - Corrective actions are intended to stop the re-occurrence of an identified problem or nonconforming work. Hence the root cause(s) of the problem has to be identified, and then appropriate action(s) can be identified and implemented to eliminate or reduce the cause of the problem identified. Corrective actions will be proportional to the risk caused by the problem identified.
- **Preventive actions** - Preventive actions will be treated in the same method as corrective actions as they are intended to prevent a problem or non-conformity occurring, as opposed to a 'corrective action', which is intended to prevent reoccurrence of a problem. These may be technical or managerial actions.
- **Audit Observations** - A relevant manager will evaluate audit observation and improvement suggestions, and will either agree to an action being implemented or reject it, giving reasons why, which will be recorded.
- **Quarantine** - Is a location where a faulty product or part is placed and labelled until it is rectified, scrapped or disposed of.