# compliance management

## policy

Compliance Management (CM) procedures (previously known as Change Management) are used to record, manage and review non-conformances (e. g. internal non-conformances, adverse events, customer feedback, supplier issues, unplanned deviation and recalls), planned procedural deviations, corrective and preventative actions (CAPA) and change controls (e.g. changes processes, critical materials, documents and equipment), to ensure that the required specifications for product quality and safety are met.

## scope

This procedure provides an overview of the Quality System processes by which *(Insert manufacturer’s name)* records and investigates:

* Non-conformances
* Planned deviations
* Corrective and Preventative actions (CAPA)
* Change Controls

## Responsibilities

The responsibilities of the Quality Manager, Quality Coordinator and Facility Director for the Compliance Management system are documented in *Quality Management.*

The Quality Manager (or delegate) is responsible for authorising each stage of the CM reports and report closure.

## Procedure

Any staff member can initiate a CM procedure at any time. During the reporting process, the information is entered into the Compliance Management module in *(Insert name of quality software application)* by a competent staff member, granted the required *(Insert name of quality software application)* permission (e.g. Quality Manager, Quality Coordinator, Scientist in Charge). The information is entered as early as possible in the process; refer to *(Insert name of quality software application document)* for detailed instructions.

If *(Insert name of quality software application)* is unavailable, a *Compliance Management Form* is used to manually record the relevant information. The information is then transferred to *(Insert name of quality software application)* as soon as possible.

**Compliance Management Numbering:**  The Compliance Management Module in *(Insert name of quality software application)* allocates a CM number. The CM number generated by *(Insert name of quality software application)* consists of:

* the prefix: CM (abbreviation for Compliance Management Process)
* followed by a sequential number

Non-conformances

Non-conformances are defined as the non-fulfilment of a specified requirement. Product, material, process, documentation, environment/facility or equipment can be identified as non-conforming at any stage. The source of a non-conformance can be from any of the following:

* Adverse event
* Audit (external or internal),
* Internal operations
* Unplanned deviations (deviations discovered after the procedure has been carried out)
* Customer feedback
* Supplier
* Recalls

Non-conformances are identified, documented, reviewed and approved as documented in *Non-Conformance Management*. Details of the non-conformance and any investigations and actions taken in response, are recorded on a non-conformance report generated by *(Insert name of quality software application)*.

The following summarises the non-conformance process:

1. Non-conformance identified and reported to the Quality Manager
2. Non-conforming product/material quarantined
3. Non-conformance report initiated
4. Immediate corrective action implemented
5. Severity of non-conformance assessed:

* **Critical:** a direct and adverse impact on the integrity, quality or safety of a product.
* **Major:** has the potential to affect the integrity, quality or safety of a product.
* **Minor:** does not have the potential to affect the integrity, quality or safety of a product.

1. Implications/impact assessed. For major non-conformances a risk analysis is performed, refer to *Risk Management*
2. Root Cause identified, refer to *Root Cause Analysis.*
3. If required, implement Corrective or Preventative Actions, refer *to Corrective & Preventative Actions*.
4. Follow up evaluation
5. Management review
6. Non-conformance closed

### Planned Deviations

Planned deviations occur when an unexpected event prevents a procedure from being followed. Planned deviations must be evaluated and authorised by the Quality Manager (or delegate) prior to implementation.

Deviations must not have an adverse impact on the final product.

A description of the deviation and the deviation justification is documented on a non-conformance procedural deviation report. Planned deviations are categorised as non-conformances, as the deviation involves a change to a documented procedure.

Corrective and Preventative Actions (CAPA)

Corrective and preventative action procedures are implemented following the identification of actions required to eliminate root causes of non-conformances, or the occurrence of potential non-conformances. Corrective action is not the immediate corrective action taken to address a non-conformance, but long term corrective actions, planned through investigation, to eliminate root causes of non-conformances, refer to *Corrective & Preventative Actions* for more detailed information. CAPA is documented using the *(Insert name of quality software application)* Compliance Management module, refer to *(Insert name of quality software application document)*.

The following summarises the CAPA process:

1. Requirement for CAPA determined by Quality Manager (or delegate)
2. CAPA initiated in *(Insert name of quality software application)*
3. Personnel and time frame assigned to CAPA action
4. CAPA Implemented
5. Follow up evaluation
6. Management review
7. CAPA action closed

Change Control

Change control procedures are used to evaluate and document all changes to processes, critical materials, documents & equipment. The potential impact of changes on the quality of the product are evaluated and approved by the Facility Director, Quality Manager or delegate and, if medically relevant, the Medical Director before implementation.

Changes are documented, implemented, reviewed and approved according to *Change Control* and are documented using the *(Insert name of quality software application)* Compliance Management module.

The following summarises the Change Control process for processes, critical materials, equipment and documents:

1. Proposed change identified.
2. Change control report initiated.
3. Severity determined: major or minor.
4. Implications/impact assessed.
5. Regulatory agencies (TGA) notified, as applicable.
6. Change approved/rejected.
7. Process Validation/ Equipment Qualification.
8. Document changes implemented.
9. Staff training.
10. Change implemented.
11. Follow up evaluation.
12. Management review.
13. Change control closed.

## management review / trending

Compliance Management reports are to be reviewed at the monthly *(Insert manufacturer’s name)* Management Review meeting.

New compliance management reports, initiated since the last meeting, are to be discussed. The following information is to be provided by the Quality Co-ordinator for review.

**Non-conformances**

* Description of non-conformance
* Immediate corrective actions implemented
* Severity
* Progress / outcomes of impact assessments/implications conducted to date
* Progress / outcomes of root cause investigations conducted to date.

**Corrective and preventative actions**

* Actions raised and personnel assigned to action
* Actions completed
* Effectiveness of any actions implemented

**Planned Deviations**

* Description of planned deviation
* Deviation justification
* Impact assessment/implications conducted to date
* Root cause investigations conducted to date

**Change Controls**

* Summary and approval status of new changes requested
* Actions implemented and personnel assigned to action

The progress of outstanding compliance management reports is discussed, including a review of the time frame targets for CAPA actions.

The results of the review are recorded in the meeting Minutes and on the relevant CM report.

### Compliance Management Statistical Analysis

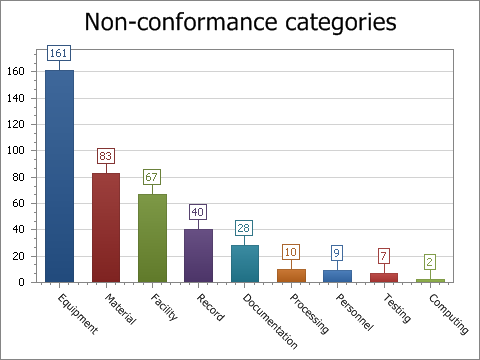
Compliance Management reports are to be statistically reviewed every 3 months, at the *(Insert manufacturer’s name)* Management Review Meetings to enable identification of any trends.

The following data is reported / charted cumulatively for the year to date, by the Quality Co-ordinator.

Annual data is to be reviewed and compared to prior years at the annual product review meeting, refer to *Product Review*.

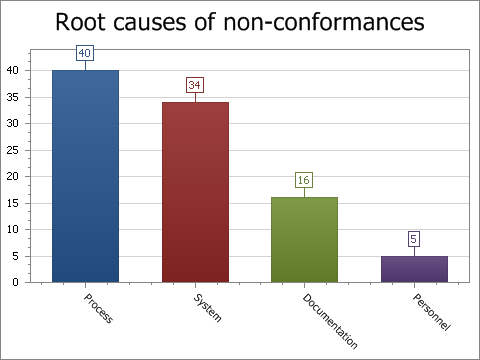
Number of non-conformances for each category.

For example:



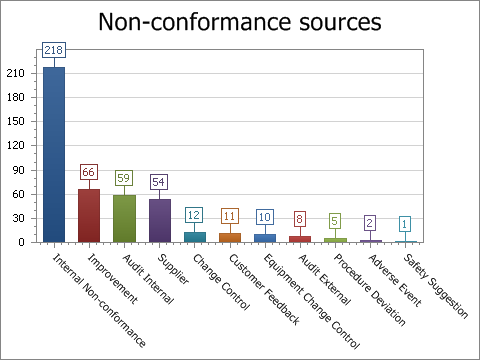
1. Root causes of non-conformances.

For example:



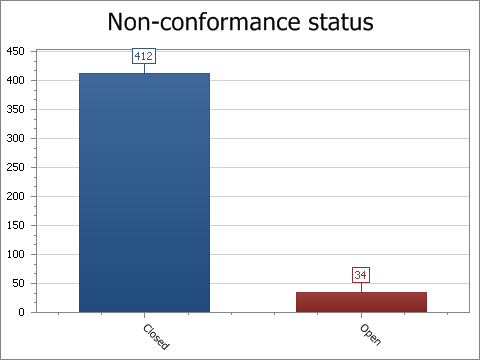
1. Sources of Compliance Management reports.

For example:



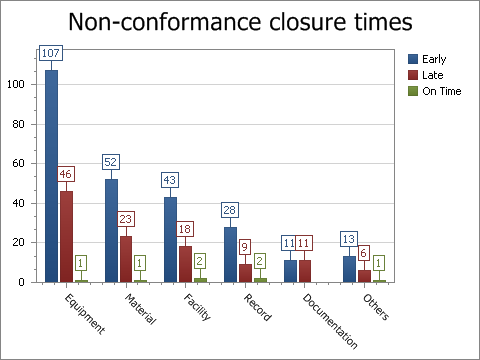
1. Status of non-conformances.

For example:



1. Closure times of Compliance Management reports.

For example:



## Records

Compliance Management reports and forms are filed in the CM Report files stored in the office of the Scientist in Charge.

## Documents

*Change Control* DOC155

*Correction & Preventative Action* DOC154

*Non-conformance Management* DOC153

*Product Review* DOC152

*Quality Software Application* DOCXX

*Quality Management* DOC50

*Recall and Product Alert* DOC69

*Risk Management* DOC53

*Root Cause Analysis* DOC156

## forms

*Compliance Management Form* FORM79

*Risk Management Form* FORM133

## Procedure History

| Revision | **Date** | **Modification** | **Approved** | **Implemented** |
| --- | --- | --- | --- | --- |
| 1.0 | *(Insert date)* | Originally drafted by (*Insert name*) | (*Insert name*) | (*Insert date*) |
| 2.0 | *(Insert date)* | Revised by (*Insert name & description of changes*) | (*Insert name*) | (*Insert date)* |