# Root cause analysis

## Purpose & SCOPE

The purpose of this standard operating procedure is to describe the problem solving process used by *(Insert manufacturer’s name)* to determine the root cause(s) of non-conformances. Identification of root causes of non-conformances is necessary in order implement effective corrective actions to prevent recurrence or the occurrence of non-conformances. Root Cause Analysis is integral part of *(Insert manufacturer’s name)* Compliance Management Processes, refer to *Compliance Management.*

## Responsibilities

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

Root Cause Analysis specific responsibilities:

* The Quality Manager (or delegate) is responsible for implementing and co-ordinating root cause investigations.
* All staff members are responsible for participating in investigations as required.

## Procedure

### Data Collection

Gather the following initial information and record it on the Compliance Management report related to the root cause analysis investigation:

* Date & location of the incident
* Source (e.g. Adverse Event, Audit (internal/external), Customer Feedback, Planned Deviation, Internal, Recall, Safety or Supplier)
* Category (e.g. Computing, Documentation, Equipment, Material, Personnel Management, Processing, Record, Testing)
* Process (e.g. Collection/Receival, Facility Management, Manufacturing, Process Controls, Quality Management)
* Product (e.g. HPC)
* Description of the non-conformance requiring the root cause analysis investigation and the name of any personnel involved
* Applicable procedures

### Interview Personnel

Interview all personnel involved in the non-conformance as soon as possible once a non-conformance has been detected.

Ask them to describe the circumstances of non-conformance.

Discuss the facts gathered during the data collection process with the relevant personnel to correct any misunderstandings or allow recollection of further information.

### Root Cause Identification

The root cause of a non-conformance may be determined using one or more of the techniques listed below.

The level of effort undertaken for root cause analysis is to be commensurate with the severity of the non-conformance. For minor non-conformances which have occurred in isolation, the root cause investigation may be limited to a discussion with the person reporting the non-conformance and an analysis of the data collected.

For a recurrence of minor non-conformances, a major non-conformance or when root cause analysis is employed as part of CAPA, one or more of the following methods / tools may be employed.

* **Brainstorming**

Hold a meeting with relevant personnel or consultants who have familiarised themselves with the incident. Participants are to put forward ideas of possible influencing factors. Once ideas of any possible influencing factors have been exhausted, the group is to collectively go through the list of ideas gathered, to assess the likelihood that each is a causative factor, and prioritise the response required for each.

* **5-Why’s Analysis method**

The 5-Whys analysis method is used to dig below the outward symptoms of a problem in order to find the real root cause.

The method involves asking the question “Why….?” five times in succession. The investigator is responsible for determining the right question to ask. It may not always be possible to ask the next question immediately. In this case further information may need to be gathered.

For example, the following questions may be asked following a report that frozen FCS has accidently thawed:

Why did the FCS thaw out? “The fridge temperature spiked”

Why did the fridge temperature spike? “The door was left ajar”

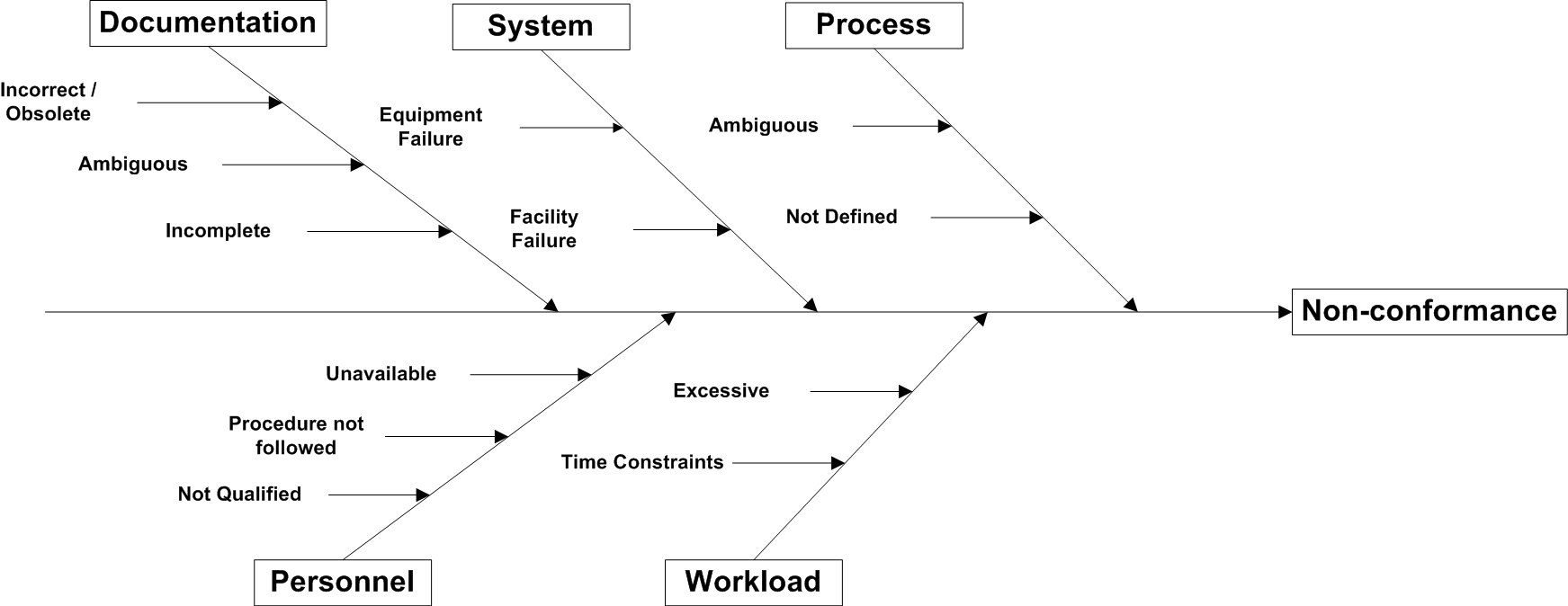
Why was the door left ajar? “Personnel were busy and forgot to close it”

Why did the personnel forget to close it? “Only one person was there and they were performing multiple processes”

Why was there only one person? “Two staff were on leave, and two were sick” **(Root Cause)**

* **Fishbone diagrams**

Where a non-conformance may have many potential influencing factors or causes the following fishbone diagram is used to break down (in successive layers of detail) root causes that potentially contribute to a particular effect.



## Root Cause classification

Where possible root causes are classified into the following categories to enable consistency across all non-conformance investigations.

### Documentation

* Ambiguous
* Incomplete
* Incorrect/obsolete

### Personnel

* Not qualified
* Procedure not followed
* Unavailable

### Process

* Ambiguous
* Not defined

### System

* Equipment failure
* Facility failure

### Workload

* Excessive
* Time constraints

Record all root causes in the Root Cause Investigation stage on the non-conformance report.

Record the main root cause identified in the Root Cause Field on the report.

**Records**

Retain hard copies of the non-conformance reports and any supporting documentation in the CM Report files located in the office of the Scientist in Charge.

**documents**

*Compliance Management* DOC148

*Quality Software Application* DOCXX

*Quality Management* DOC50

## 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)* |