



**DATE: 12TH January 2020**

**OPERATING PROCEDURE**

**OP-12**

**REV NO: 07**

**NON CONFORMANCE, CORRECTIVE ACTION, PREVENTIVE ACTION MANAGEMENT**

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## REVISION RECORD

REVISION NUMBER	REVISION DATE	DETAILS OF REVISION
01	31.12.02	Document reviewed to reflect requirements of EN ISO 9001 : 2000 and reissued in entirety
02	12.10.14	Job titles amended to reflect current status
03	12.01.16	Form QA -07 Revised
04	03.05.16	Document reviewed to reflect requirements of ISO/IEC 17020:2014 Form re numbered
05	12.03.17	Complete review and combines OP 12 and 13.
06	06.02.18	Update to clarify who conducts investigations on appeals, informing interested parties and management of potential non-conformities (risks)
07	12.01.20	Updated process map.

## 1.0 INTRODUCTION

This procedure describes the method of raising non conformances from multiple sources. The likely sources are detailed after the process map. The procedure details the process of managing non conformances, Corrective and Preventive actions..

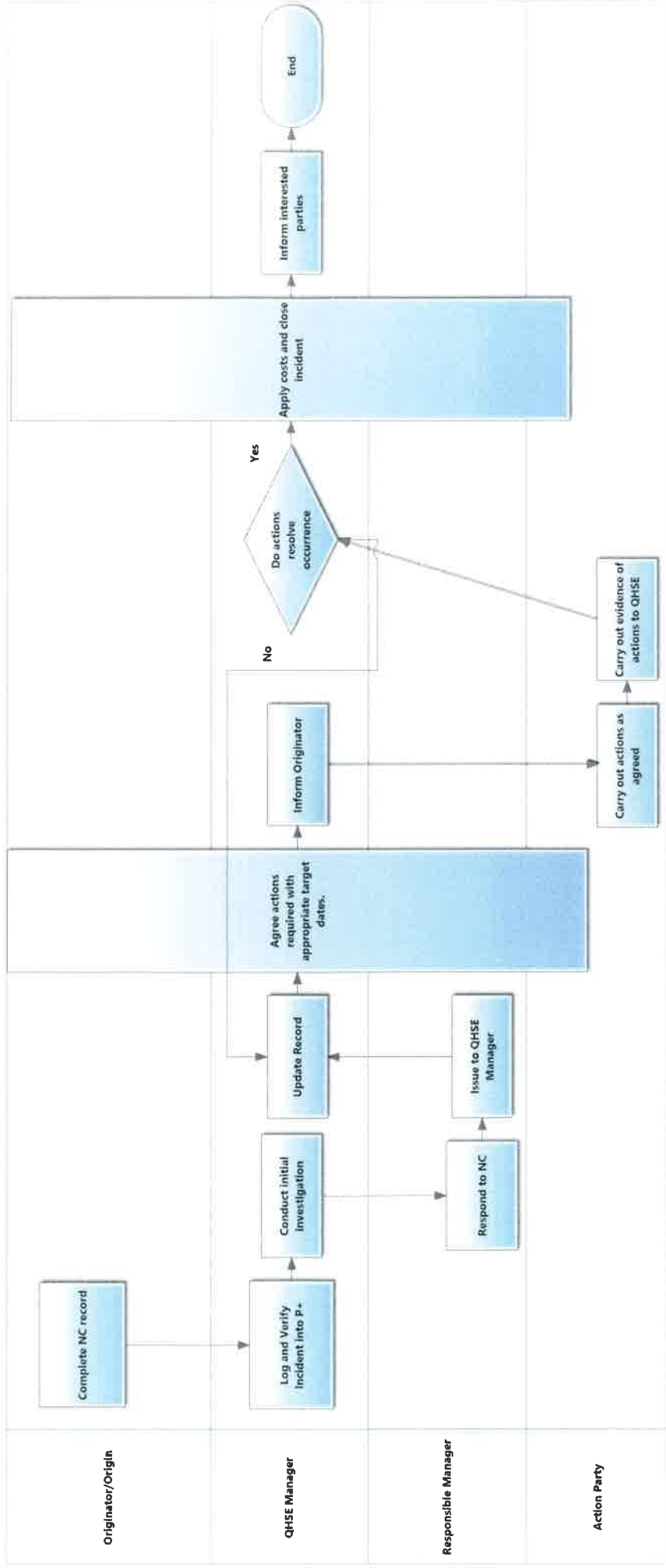
## 2.0 DEFINITIONS

NON CONFORMANCE	Is a deviation from a specification, a standard, or a requirement. Non-conformances can occur with respect to specific requirements of a product, process or standard. A non-conformance may include, but is not limited to: <ul style="list-style-type: none"><li>• Deviation from the standard operating procedure, manual, contract requirement, etc.</li><li>• Discrepancy relevant to a component or a part</li></ul>
OFI	Opportunity for Improvement. An action notified which may improve a process, procedure, records, but not yet a non conformance.
CONTAINMENT ACTION	Is the first action taken while a root cause analysis is underway. It is the initial action taken to resolve the immediate impact of the issue.
ROOT CAUSE	The most basic cause that can reasonably be identified that management has control to fix and, when fixed, will prevent (or significantly reduce the likelihood of) the problem re-occurring.
CORRECTIVE ACTION (CA)	Is a reaction to a cause or multiple causes for a non-conformance, which requires resolution. Corrective action is taken to prevent reoccurrence.
PREVENTIVE ACTION (PA)	Is an action taken to eliminate the cause of a potential nonconformity or other undesirable potential risk. Preventive action is aiming to determine present and future risks to avoid the potential occurrence of a non-conformance by proactively implementing improvements
APPEALS	Request by the provider of the item of inspection for reconsideration of a decision it has made relating to that item

## 3.0 PROCEDURE

A process map followed by clarifications follows.

## Non Conformance Process



1 As noted on the process map occurrences can be identified from many sources. The originator may be any of the following:

- Internal audits.
- Third Party audits.
- Supplier audits.
- Customer complaints, feedback reports, whether negative or positive.
- Internal feedback reports.
- Any employee who discovers any deviation, improvement idea, process improvement etc.
- Actions from Management Reviews, where appropriate
- Appeals - Request by the provider of the item inspected for reconsideration of a decision it has made relating to that item.
- Potential non conformities (risks)

The form can be completed directly into the database, electronically or communicated through e-mail to the HSEQ department. The originator need only complete the detail section of the form as HSEQ process the action further, prior to distribution to the appropriate parties. Actions are verified by HSEQs who ensure that the NC or CAPA is valid.

The detail of non-conformance should be specific and based on fact, not perception. The following questions should be considered:  
*Who? What? Where? When?*

In the case of complaints the acknowledgement is sent to the originator. Customers can have access to complaints relating to their organisation at any time by contacting the HSEQ department. In some cases GIS use the customers systems and as a result the whole process is visible to them.

This list is not exhaustive and the intention is to follow the same process for all system and process related issues.

2 NC's and CAPA are reviewed by the HSEQ department and the occurrence logged in a database. The database automatically assigns a sequential number upon an Incident being successfully raised.

- 3 The HSEQ department conduct an initial assessment and allocate the team to deal with the NC, CAPA. In considering the personnel to conduct an investigation the technical competence is critical. An example is appeals where the investigator must be competent in the discipline in question. The occurrence is categorised in terms of:

Department	The department involved in the occurrence.
Process	High level process e.g. document control, record management, competency etc.
Source	The source of the occurrence as described in 1 above.
Fault category	High level fault categories e.g. process not clear, process not implemented
Owner	The person with the authority to deal with the occurrence as appropriate.
Root Cause	If appropriate at this point a main root cause is selected. This is not to be mistaken for the multiple root causes which may arise from a Taproot® investigation (Taproots are generally full investigation report for significant issues.
Cost of Poor Quality (COPQ)	As appropriate at this point

This information is utilised to identify trends, by each of the headings and over differing periods to identify improvement opportunities based on facts.

- 4-5 The Responsible Manager is likely to be the owner and will respond to the occurrence. There are various responses but the HSEQ will aim to update the records at least monthly as required. In some cases e.g. Opportunities for Improvement there may be no action required, but in most cases further action will be required.
- 6 Actions appropriate to the occurrence and associated root causes, where applicable, are raised and realistic target dates agreed. This information is then passed to the personnel responsible for conducting them. There are various categories of action e.g., Verification, Containment, Root Cause Investigation, Risk Assessment Corrective Action, Preventive Action, Effectiveness Review etc. and there may be sub actions and multiple

personnel involved in each stage. The HSEQ department update the database with this information.

When considering the extent of work involved in actions the following is considered:

- What is the likelihood of recurrence?
  - What is the potential frequency?
  - What effect is there on business objectives and customer perception?
  - What costs could be involved in corrective action if the issue occurred?
  - Can the potential issue be removed or overcome?
  - Is the cost of preventive action realistic when compared to the effect?
  - What action is necessary to remove the problem?
- 7 The originator is informed at this point. Interested parties (e.g. other sites which could be impacted, customers, if required, or Senior Management) may be informed as necessary.
- 8-9 The actions are to be completed as agreed. If for any reason actions will not be completed in the agreed timescales, the HSEQ department must be informed to update the database.
- 10 If the actions do not resolve the occurrence the actionees must re-review the potential root cause and further action, if required to close the action.
- 11 If appropriate, the HSEQ department will apply costs to each stage of the occurrence and to where each part of the cost is allocated. Examples are credit notes, downtime, failure costs, CA costs etc.

Although estimated in many cases the information will provide further analysis in addition to the number of occurrences.

Once all action stages have been completed and prior to Incident closure it may be appropriate to add the resolution from the available list in the database.

- 12 Inform interested parties of the closure of the actions and any actions taken to resolve the occurrence. Interested parties may be the originator (including customer where complaints have been raised, or it is a requirement to inform them), owner, stage owners, other parts of the



organisation which may benefit from the actions taken and area of the business impacted by any changes which may have taken place. A decision to conduct effectiveness reviews is determined at this point.