



Guidance Notes: Corrective Action Plans

Completion of the IMS Corrective Action Plan

During an assessment carried out by IMS International the audit team may have identified non-conformances within your system and procedures that require submission of a corrective action plan (IMS International Form 10).

It is essential that you complete the Corrective Action Plan correctly and in sufficient detail to give confidence to the certification team that the non-conformances have been suitably addressed in terms of root cause analysis and effective long term corrective actions and that the non-conformance will not reoccur.

Please use this guidance document and others available on the IMS website to aid in the completion of the Corrective Action Plan. Incorrect or incomplete completion may delay certification being granted or continued.

Only supporting information and objective evidence necessary to understand and close the non-conformances shall be attached to the Corrective Action Plan response. Be certain to clearly identify any attachments.

Immediate Corrective Action Taken

Describe the actions taken immediately to:

- Stop the non-conformance from continuing
- Assess the damage
- Segregate impacted product
- Notify as appropriate

These actions address the immediate or direct cause of the non-conformance only, and really only contains the problem. An example of immediate corrective action may be as follows:

Non-conformance; Supplier evaluation not complete and supplier subsequently not on the Approved Supplier List

Immediate Corrective Action; Supplier sent evaluation questionnaire, received, reviewed and approved them for use, supplier included onto the approved supplier list. A review has been carried out of all current suppliers to ensure that they have been put through the formal evaluation process and they were all found to be compliant.

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Root Cause of the Non-conformance

Investigate all causes contributing to the non-conformances using root cause analysis techniques such as 5 Whys technique, fish bone diagrams, cause chains, or similar tools. Guidance documents are available on the IMS website to aid in the Root Cause Analysis (Doc 6f) process and guidance is also available on some of the techniques used such as 5 Whys (Doc 6i). The root cause will need to identify how or what caused the non-conformance to arise. Only the identified Root Causes should be included on the response and details of how you got to the root cause should be included. Supplemental information to support your cause analysis may be included as objective evidence if necessary for understanding.

An example of the 5 Whys technique to investigate the non-conformance above follows:

- **Why** was the Supplier evaluation not completed?
 - *The Supplier was not sent an evaluation questionnaire*
- **Why** was the supplier not sent a questionnaire?
 - *No one was aware of the new supplier.*
- **Why** wasn't anybody aware of the new supplier?
 - *A new employee introduced the supplier to the system*
- **Why** did the new employee add the supplier to the system without having them approved?
 - *The employee placing the order with the supplier was not aware of the system in place.*
- **Why** was the employee not aware of the system in place?
 - *RC-The training system for new employees did not cover this process*
 - *RC-There is no system in place for prompting/stopping an employee from purchasing from someone who has not gone through the approval process*
 - *RC-There is not a single person responsible for issuing out evaluation questionnaires and subsequent approval onto the system*

Long Term Corrective Actions

Long term corrective actions need to be implemented to prevent the root cause issues from re-occurring. Consideration of actions necessary to address all identified causes is required. For example:

- *A new training programme has been developed for all new employees within the organisation that focuses on specific documented procedures. All employees will be tested against the procedure and a record of the results maintained and identified on the skills matrix*
- *The purchasing manager has been given responsibility for the introduction of new suppliers onto the system and will send out all evaluation questionnaires as requested by employees. A roles and responsibility matrix has been produced*

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which covers all activities of the organisation and will define the responsibility for each of the stated activities.

- *The purchasing software has been reviewed and new passwords issued to employees with different levels of access to the system. No employee is able to add a new supplier to the system; the system will not allow them to and will display a message. The Purchasing Manager is the only employee who has access to this area. A log has been implemented to record and track any questionnaires sent out to new suppliers and will chase where appropriate.*

Objective Evidence

Objective evidence of implementation of corrective actions shall be attached to the submittal where requested. Please ensure that you clearly identify which non-conformance the piece of evidence is related to. Evidence to support the example above may include:

Objective Evidence Submitted:

- *Completed Supplier Questionnaire for missing record*
- *Training record for all employees within purchasing department and updated skills matrix*
- *New roles and responsibilities matrix*
- *Screen dump of the message that is generated when someone attempts to add a new supplier*
- *Log for tracking questionnaires issued*
- *The record of the review of all suppliers to ensure they have submitted a questionnaire and been approved*
- *Internal audit of the updated process to demonstrate the system is in compliance*

Responsibility

The Auditee needs to define who is responsible for implementing the corrective actions, this may be the Quality Manager but it could be delegated to someone else within the organisation.

Due Date

The date when the corrective actions and/or procedure revision becomes effective. This date needs to be realistic but within a reasonable time frame.