C/A INSTRUCTIONS/CLIENT REMINDER LIST

Guidelines for corrective action submissions for clients

CORRECTIVE ACTION INSTRUCTIONS

1. All corrective actions, including evidence to demonstrate verification of implementation, need to be completed before the due date.
2. Corrective actions must comply with the subscribed standard.
3. You may use your own corrective action process/format.
4. Keep copies of the complete corrective action submission for your records. Have them available on-site for your next audit.

Submit your corrective action package directly to your Lead Assessor via email, or via iEnable portal whichever is more convenient

Corrective action guidelines:

Per ISO 9000:2015

- Correction: action to eliminate a detected nonconformity
- Corrective Action: action to eliminate the cause of a detected nonconformity and to prevent recurrence.

Correction

- Correction should be written in the past tense (meaning that correction was implemented, and no non-conforming product/service is being produced/offered
- A plan can be acceptable if it provides defined responsibilities, description of deliverables and dates of implementation.
- Correction should include an assessment of the extent of the nonconformity, containment measures, and if similar occurrences were corrected (systemic correction).
- Example NCR: The calibration record for Micrometer #123 was not found.
  - Correction: Micrometer #123 was taken out of use and calibrated on dd-mm-yy. Micrometer #456 and Caliper #789 were also missing a calibration label, they were also taken out of use and calibrated on dd-mm-yy.

Root Cause

- A well-defined root cause will refrain from restating the finding or the direct cause.
- Root cause is the underlying cause of a problem, which will effectively prevent a recurrence of that problem, if adequately addressed.
- Direct Cause: “Micrometer #123 calibration record was not uploaded in the calibration recall system …” Root Cause: “… because the calibration process does not adequately define provisions for entering devices into the recall system.”
- The root cause statement should address the fundamental issue without any additional “why” questions remaining (known as “5 Why”)
- Additional root cause analysis methods: Ishikawa (Fishbone) Diagrams, “Is / Is Not”, etc.

Containment

This should normally go in the "correction" section of the finding report. The client must stop the defect at each point and take immediate containment action

When auditor accepts corrective action plan per 17021-1:2015, the client must submit evidence, and the auditor must document a statement of what containment evidence was looked at for closure.

Corrective Action

- *Corrective actions will eliminate the cause of the nonconformity.*
- *If more than one root cause is defined, corrective actions must address all causes.*
- *The response should demonstrate how recurrence will be prevented and what evidence will need to be collected to demonstrate prevention of recurrence*
- *Evidence of implementation will demonstrate that defined actions have been implemented.*

Example of corrective actions: The calibration process was revised to include provisions for adding new devices in the recall system and personnel was trained on the new process

Evidence: 1) Revised process, 2) record of training on new revision 3) records of new measuring devices entered in the recall system

Verification of Effectiveness

- Plans for verification of effectiveness shall identify a timeline that includes responsibilities and describe evidence necessary to demonstrate prevention of recurrence
- Example of effectiveness verification:

Finding: Internal audits not conducted as per internal audit programme

Occurrence Cause 1: Internal audit dates were not updated in the internal audit programme due to process not followed and procedure not clear

OC1 Corrective Action: Develop work instruction to define how the internal audit programme is to be developed

Verification of effectiveness: Evidence collected show internal audit programme issued and approved in time, before the beginning of the new year, and internal audits scheduled as per programme; based on interviews conducted, personnel in charge of issuing the internal audit programme and ensuring its' implementation, are aware of the process and their responsibilities and expectations are clearly understood.

CLIENT REMINDER LIST

Additional Corrective Action Requirements:

- Intertek expects to receive corrective action responses within the required time frame.
- On-site reviews may be scheduled if corrective action responses are not received within the required time frame or certificate may be suspended
- Lack of evidence to demonstrate verification of corrective actions implementation and effectiveness may result in a major nonconformance being issued or suspension
- To ensure continuous certification, all corrective actions addressing major non-conformities must be implemented and effectiveness verified before the expiry date on the certificate. For minor

non-conformities, all corrections must be implemented and verified, and corrective action plan approved before the expiry date on the certificate

Additional Corrective Action Requirements (Multi-sites):
Although nonconformities may have been observed at one site only, there is a potential for the same nonconformity to also apply to all sites of a multi-site organization where the same activities and/or processes take place. Therefore, the corrective action plan of the client, in addition to the other requirements of the corrective action process, shall address the following:

- Provision of objective evidence of the evaluation of the nonconforming situation at all sites;
- Identification of the sites where the nonconforming situation exists;
- Objective evidence of implementation and verification of effectiveness of corrective action at all sites.

Please also visit www.intertek.com/business-assurance/ for any complaints, appeals or concerns you may have.