CORRECTIVE ACTION

Background of terms

Corrective actions are powerful tools of continuous improvement in quality management systems such as ISO/IEC 17025 and ISO 9001.

Corrective action is an activity that shall be used to stop the re-occurrence of these non-conformities or the occurence of similiare non-conformities.

Corrective action has to be initiated when a problem exists. Remedial action can easily be confused with corrective action. Remedial action is taken to rectify the mistake. Corrective action is an action to eliminate defined non-conformities.

Example:
To recall a test report and make necessary changes is a remedial action because making changes in the report does not help to prevent re-occurrence of non-conformities.

Corrective actions are defined in ISO/IEC 17025 article 8.7, respectively.

Identification and classification of non-conformities

Identification of non-conformities is the key process and shall be well defined in quality systems.
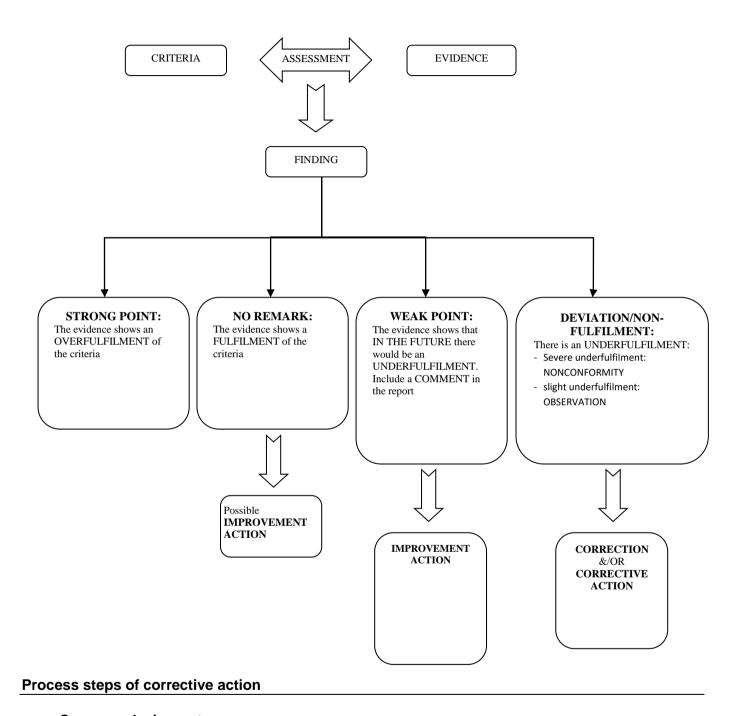Non-conforming laboratory activities is described in article 7.10 of ISO/IEC 17025.

Where the evaluation of the nonconforming work indicates that it could recur the laboratory shall implement corrective action. Same is when there is a doubt of the laboratory´s operations with its own management system.

It should always be considered whether the collected data are useful for the purpose. If data are collected and classified correctly, this activity will help to identify the problems clearly.

During the classification process, the priority and significance of non-conformities shall be evaluated.

The audit, client or normative criteria are assessed against the evidence found by the client, the internal/external auditor, or laboratory staff. The assessment can conclude that there are several different cases:

CRITERIA	ASSESSMENT	EVIDENCE

FINDING

STRONG POINT:	NO REMARK:	WEAK POINT:	DEVIATION/NON-FULFILMENT:
The evidence shows an OVERFULFILMENT of the criteria	The evidence shows a FULFILMENT of the criteria	The evidence shows that IN THE FUTURE there would be an UNDERFULFILMENT. Include a COMMENT in the report	There is an UNDERFULFILMENT: - Severe underfulfilment: NONCONFORMITY - slight underfulfilment: OBSERVATION

Possible **IMPROVEMENT ACTION**

IMPROVEMENT ACTION

CORRECTION &/OR **CORRECTIVE ACTION**

Process steps of corrective action

- **Cause analysis, root cause**

ISO 17025 Standard indicates that the corrective action process starts with a cause analysis. Cause analysis is the important and most difficult step in the process. Any kind of mistake in this step may cause the implementation of wrong corrective action and does not avoid re-occurrence of non-conformities.

The initial step of cause analysis is organizing a "corrective action team" consisting of laboratory staff familiar with the problem.

All potential causes should be evaluated by brainstorming discussions by the "corrective action team" in order to define the root cause. The team should consider all circumstances related to the problem such as personnel, equipment, chemicals, training etc. but they should always remember that the primary aim is to find the root cause.

Analyzing non-conformities effects and needs for action
The impact of non-conformities on laboratory work should be analyzed carefully. To update the risks and opportunities the possibility of recurrence and end effect on a routine procedure should be determined. Some of the non-conformities may not have the chance of recurrence or no effect on the procedures. The Corrective Action Team should decide what kind of action has to be taken.

Corrective actions can be implemented either during one special event or during recurrent events according to the severity and the priorities of non-conformities.

Selection and implementation of corrective actions
The laboratory shall implement corrective actions if neccessary after the decision of the Corrective Action Team.

Necessary conditions for corrective action should be clearly defined. The laboratory management should be confident about the effectiveness and the performance of the corrective action.

Monitoring of corrective actions
The result of the corrective actions shall be recorded and monitored for determining the effectiveness of the corrective actions. Monitoring should verify the successful completion of the identified actions and assess the effectiveness of the actions taken.

Monitoring of reccurrences of non-conformities after the implementation of corrective actions is one of the key performance indicators for corrective action process.

Monitoring may also requires additional audits if identified non-conformities cause serious doubts about a laboratory's compliance with standards, its own policies and its own procedures.

References
[1] ISO/IEC 17025:2017, "General requirements for the competence of testing and calibration laboratories"
[2] Hoyle, D. ISO 9000:2000 An A-Z Guide Butterworth-Heinemann An imprint of Elsevier Science Linacre House, Jordan Hill, Oxford OX2 8DP 225 Wildwood Avenue, Woburn, MA 01801-2041, 2003.
[3] ISO 9000:2015, "Quality management systems-Fundamentals and vocabulary"

ANNEX

CORRECTIVE ACTION FORM				
NO	011	DATE	11.02.2018	REQUESTED BY	Quality Manager
RELATED EMPLOYEE		Instrumental Laboratory Chief		RELATED DEPARTMENT	Technical Department

Non-conformities
Customer objects to vitamin A results in 12345 sample. Result is 0.64 mg/kg.

Causes of non-conformities
The analysis process was checked by the analyst and the Instrumental Laboratory Chief against the written and original method (EN 12823-1:2014). Calculation steps were controlled by following the described method. HPLC conditions (column, flow rate, mobile phase) were suitable. Differences between parallel results were lower than the repeatability limit. The last quality control sample (spiked sample) had been worked one-week (02.02. 2018) prior to the study sample. The results were within acceptable limits.
During the conversation with the analyst, it was discovered that the standard concentration was not controlled with a spectrophotometer before the analysis. Although this control is written down in the test procedure, the analyst skipped this step and relied on the last quality control study.
The analysis was repeated and the standard concentration was controlled with a spectrophotometer. The result has changed to 0.72 mg/kg , which was inside the customer expectation range.
Root cause: The standard concentration has decreased and was not controlled during the analysis.

Planned correction (remedial action)
The report was revised and new report was sent to the customer.

Do the non-conformities result in a need to implement corrective action?
Yes ☒   No ☐

Planned corrective action
The analysis methods will be revised and a standard control sheet for vitamin A will be added to the procedure. Experience which was gained from this non-conformity is written in the analysis methods under the headline "important note". Training will be given to each employee in the laboratory regarding the importance of standard concentration control.

Planned finishing date	Finished date	Evaluated by
16.02. 2018	16.02. 2018	17.02. 2018/Quality Manager

Evidence for effectiveness
Revision of the analysis method has been controlled. Training records were checked.
Spectrophotometer control has been applied by the analyst and checked with the method for evaluation.

CORRECTIVE ACTION FORM					
NO	023	DATE	05.04. 2018	REQUESTED BY	Quality Manager
RELATED EMPLOYEE		Analytical Chemistry Laboratory Chief		RELATED DEPARTMENT	Technical Department

Non-conformities
Last internal quality control study exceeded the action limit of the protein analysis.

Causes of non-conformities

The analysis process was checked by the analyst and the Analytical Chemistry Laboratory Chief by checking the written and original method. The method steps, raw data and calculations were suitable to the methods.

- If there was a problem with the distillation equipment the results should be lower than expected. But in this case the results were higher. It seems that the problem is not related with the distillation equipment.

- The chemicals used in the analysis were evaluated. A commercial catalyst tablet was used in the analysis. The analysis was repeated with a commercial catalyst tablet and 15g K_2SO_4, 0.9 $CuSO_45H_2O$. The results obtained by using a different tablet were higher than the other catalyst in quality control samples (catalyst tablet: 12.9 %, 15 g K_2SO_4, 0.9 $CuSO_45H_2O$: 11.2 %). The result of 15g K_2SO_4, 0.9 $CuSO_45H_2O$ was within the limit. These results indicate that there seems to be a problem with the catalyst tablet.

- All samples taken between the last good result from the internal quality control samples to the bad result were reexamined. There were 20 samples within this time period. The results of three samples had been sent to the customer. All samples and the quality control sample were repeated with 15 g K_2SO_4 and 0.9 $CuSO_45H_2O$. The results obtained by both catalysts are given below:

Sample No	Sample type	Catalyst tablet results	15 g K_2SO_4 and 0.9 $CuSO_45H_2O$ results	Sample No	Sample type	Catalyst tablet results	15 g K_2SO_4 and 0.9 $CuSO_45H_2O$ results
9765	Pasta	12.8 %	10.7 %	10057	Pasta	12.7 %	10.6 %
9772	Dried bread	12.5 %	10.2 %	10062	Pasta	12.3 %	10.2 %
9973	Dried bread	12.9 %	10.5 %	10063	Pasta	12.9 %	10.7 %
9974	Dried bread	12.7 %	10.4 %	10064	Pasta	12.5 %	10.2 %
9976	Wheat flour	13.1 %	11.3 %	10074	Wheat flour	13.3 %	11.4 %
10021	Pasta	11.8 %	9.7 %	10077	Pasta	11.6 %	9.6 %
10047	Wheat flour	12.9 %	10.6 %	10079	Wheat flour	12.9 %	10.6 %
10048	Wheat flour	13.1 %	10.9 %	10080	Wheat flour	13.1 %	10.9 %
10049	Wheat flour	12.9 %	10.7 %	10081	Wheat flour	12.9 %	10.7 %

10051	Wheat flour	12.8 %	10.6 %	10082	Wheat flour	12.7 %	10.7 %	
QM sample	Wheat flour	13.1 %	11.3 %	WL: 11.5 %, AL:11.7 %				

Root cause: There is a problem with the catalyst tablet

Planned correction (remedial action)
The reports of three samples were revised and new reports were sent to the customer. Other results were corrected in the LIMS system.
Do the non-conformities result in a need to implement corrective action?

Yes ☒ No☐

Planned corrective action

Each lot of catalyst tablets will be used with QM samples and be compared with 15 g K_2SO_4, 0.9 $CuSO_45H_2O$ before being used in routine studies.

QM study frequency will be decreased to one in ten samples.

The analysis method will be revised and rules for using commercial catalyst tablets will be included in the procedure.

Training will be given to all employees that can perform this analysis

Planned finishing date	Finished date	Evaluated by
19.04. 2018	19.04. 2018	19.04. 2018/Quality Manager
Evidence for effectiveness		

QM sample records have been checked; there was a new lot of catalyst tablets; comparative results have been recorded in the laboratory book.

Training records have been checked and discussed with the analysts.

CORRECTIVE ACTION FORM					
NO	036	DATE	14.07. 2018	REQUESTED BY	Quality Manager
RELATED EMPLOYEE		Microbiology Laboratory Chief		RELATED DEPARTMENT	Technical Department

Non-conformities

Proficiency test results of Fecal *coliform* and *E. coli* results were -2.3 and -2.2 respectively in water samples.

Causes of non-conformities

The analysis process was checked by the analyst and the Microbiology Laboratory Chief against the written and original method. The sample arrived at the laboratory on 04th June 2018 and was put into the refrigerator. It was forgotten to analyze it until 14th June, 2018 (last week).

The last internal quality control study (Shewhart and range chart) was applied on 01st June 2018, before the sample was analyzed and also on 15th June 2018 and 30th June 2018, after the sample had been analyzed the same month. The results were appropriate to the values indicated in the Shewhart and range chart. Other quality control studies such as counting colonies, air and surface control results were also suitable.

There were no positive Fecal *coliform* and *E. coli* results between June 4, 2018 and June 15, 2018 in the water samples.

Root cause: The sample has been analyzed in the last few days and these may have caused problems in the results.

Planned correction (remedial action)

There is no remedial action.

Do the non-conformities result in a need to implement corrective action?

Yes ☒   No☐

Planned corrective action

One analyst will be responsible to follow each proficiency test sample when samples come to the laboratory. This analyst will trace the sample and plan the study with other analysts.

Planned finishing date	Finished date	Evaluated by
September 2018	19.09. 2018	19.09. 2018/Quality Manager

Evidence for effectiveness

New results are 1.6 and 1.3 for Fecal *coliform* and *E. coli*, respectively. The assigned employee was recorded in the laboratory book.