CORRECTIVE ACTIONS

Background of terms

Corrective actions are powerful tools for the continuous improvement of management systems, such as ISO/IEC 17025 and ISO 9001.

A corrective action is an activity that shall be used to stop the re-occurrence of these non-conformities or the occurrence of similiar non-conformities.

Corrective action shall 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:
Recalling a test report and making any necessary changes is a remedial action, as changes in the report does not help to prevent the re-occurrence of non-conformities.

Corrective actions are adressed in clause 8.7 of ISO/IEC 17025.

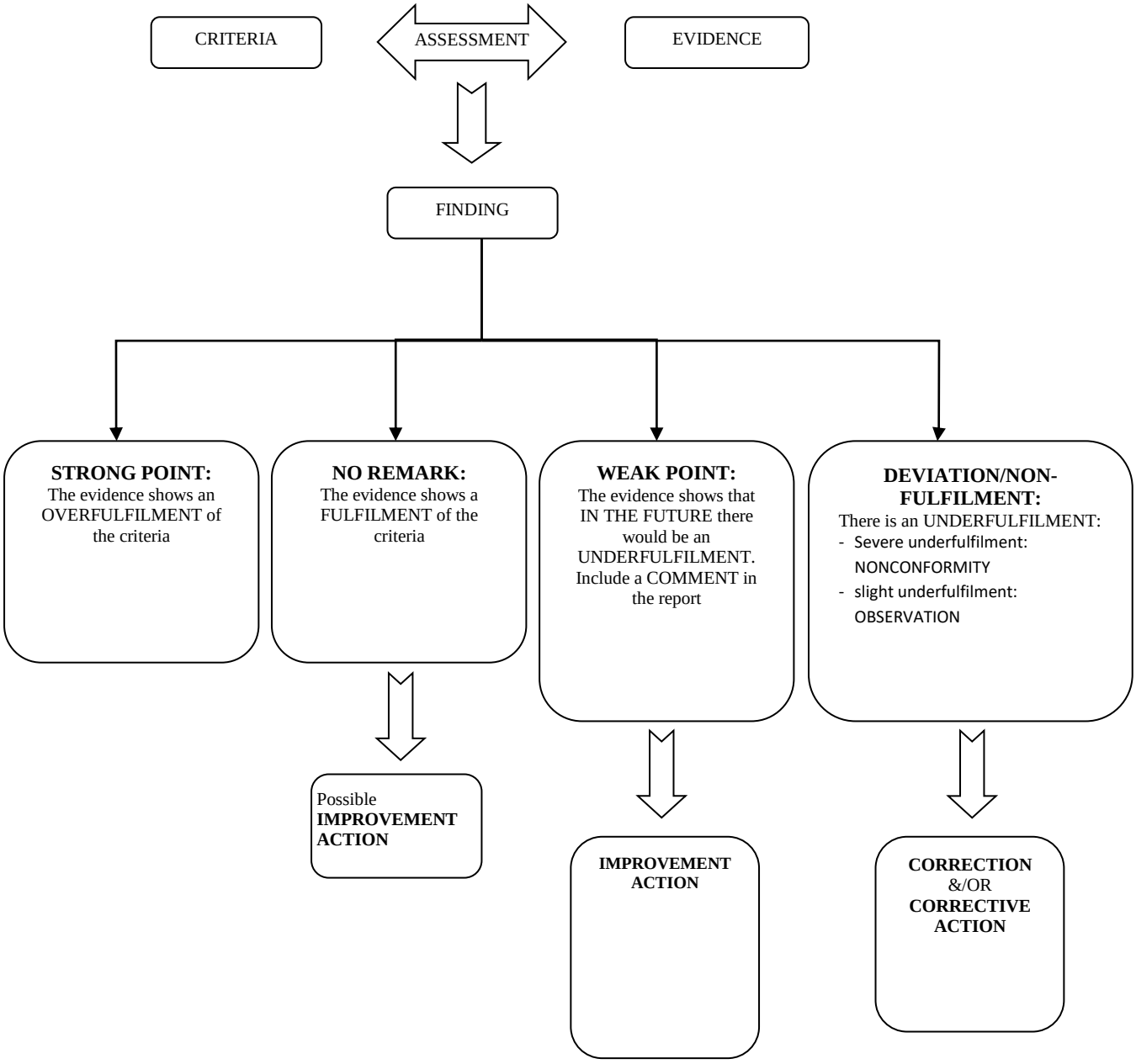
Identification and classification of non-conformities

The identification of non-conformities is the key process and shall be well defined in quality management systems.

Dealing with non-conforming work is adressed in clause 7.10 of ISO/IEC 17025. In this context, the significance of non-conformities shall be evaluated. Where the evaluation of the nonconforming work indicates a significant impact on laboratory activities the laboratory shall implement actions based upon the respective risk.
The same applies if there is doubt about 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 correctly classified, this activity will help to clearly identify the problems.

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



Process steps of corrective action

- **Cause analysis, root cause**

ISO/IEC 17025 requires that the evaluation starts with a cause analysis. Cause analysis is the important and most difficult step in the process. Any mistake in this step can cause the implementation of wrong corrective action and does not prevent the recurrence of non-conforming work.

One initial step of cause analysis can be to organize a “Corrective Action Team” consisting of laboratory staff who is familiar with the problem.

All potential causes should be evaluated by brainstorming discussions by the “Corrective Action Team” to define the root cause. The team should consider all circumstances related to the problem, such as

processes, personnel, equipment, chemicals, training needs 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. In order 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 have not a 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 specific event or during recurrent events according to the severity and 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 impact of the corrective actions shall be recorded and monitored to determine the effectiveness of the corrective actions. The monitoring should verify the successful completion of the identified actions and assess the effectiveness of the actions taken.

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

Monitoring may also require additional audits if identified non-conformities raise serious doubts as to whether a laboratory complies with the 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.

Cause analysis for non-conformities
The analysis process was checked by the analyst and the Instrumental Laboratory Chief against the written and the original method (EN 12823-1:2014). The 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) was analysed one week (02.02.2018) prior to the study sample. The results were within acceptable limits. During the conversation with the analyst, it was found that the standard concentration was not controlled with a spectrophotometer before the analysis. Although this control is recorded in the test procedure, the analyst skipped this step and relied on the latest 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 within 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 the 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 vitamin A control sheet will be added to the procedure. Experience gained from this non-conformity is described in the analysis methods under the headline “Important Note”. Each employee in the laboratory will receive training on 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 of effectiveness
The revision of the analysis method was controlled. Training records were checked. The spectrophotometer control was 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

The last internal quality control study has exceeded the action limit of the protein analysis.

Cause analysis for non-conformities

The analysis process was checked by the analyst and the Analytical Chemistry Laboratory Chief by checking the written and the original method. The method steps, raw data and calculations were suitable for 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 to 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_2SO4, 0.9 $CuSO_45H_2O$. The results obtained by using a different tablet were higher than those of the other catalysts in the quality control samples (catalyst tablet: 12.9 %, 15g K_2SO4, 0.9 $CuSO_45H_2O$: 11.2 %). The result of 15g K_2SO4, 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 re-examined. Within this period, there were 20 samples. The results of three samples were sent to the customer. All samples and the quality control sample were repeated with 15g K_2SO4 and 0.9 $CuSO_45H_2O$. The results obtained with both catalysts are given below:

Sample No	Sample type	Catalyst tablet results	15g K_2SO4 and 0.9 $CuSO_45H_2O$ results	Sample No	Sample type	Catalyst tablet results	15g K_2SO4 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	12.8 %	10.6 %	10082	Wheat	12.7 %	10.7 %

	flour				flour		
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 on 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 compared to 15g K_2SO_4, 0.9 $CuSO_45H_2O$ before use in routine studies.

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

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

All employees who can perform this analysis will receive training.

Planned finishing date	Finished date	Evaluated by
19.04.2018	19.04.2018	19.04.2018/Quality Manager

Evidence of effectiveness

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

Training records were 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* in water samples were -2.3 and -2.2, respectively.

Cause analysis for non-conformities

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

The last internal quality control study (Shewhart and range chart) was conducted on June 01, 2018, prior to the sample analysis, and also on June 15, 2018 and June 30, 2018, after the sample was analyzed in the same month. The results corresponded 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 results of Fecal *coliform* and *E. coli* in the water samples between June 4, 2018 and June 15, 2018.

Root cause: The sample was analyzed in the last few days and this 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 for following each proficiency test sample when the samples arrive at 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 of 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.