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Comments

An audit cannot cover each and every detail of the management system. Therefore, there may still be nonconformities not addressed by the auditors in the closing meeting or the audit report. Audit results are always evaluated on the basis of the following classification:

Nonconformities	Failure to fulfil one or more requirements of the management system standard or a situation that raises significant						
(NC):	doubt about the ability of the client's management system to achieve its intended outputs.						
	(Classification: Major nonconformities).						
	Corrections (immediate solution) of the audit finding are to be implemented						
	The causes of the identified nonconformities shall be analyzed						
	Corrective actions for the causes of the nonconformities shall be effectively implemented prior to						
	the decision on certificate issue/renewal						
	The auditor generally verifies the effectiveness of corrective action in an on-site re-audit unless verification						
	is possible on the basis of submitted new documentation.						
Minor	In individual cases some of the requirements of the management-system standard are not fulfilled completely.						
nonconformities	However, this does not jeopardize the effectiveness of the management-system element (chapter of the standard).						
(MiN):	(Classification: Minor nonconformities).						
	 Corrections (immediate solution) of the audit finding are to be implemented 						
	 The causes of the identified nonconformities shall be analyzed 						
	The lead auditor is to be informed of the intended corrective actions for the causes of the						
	nonconformities within 14 days prior to the decision on certificate issue/renewal						
	 The lead auditor evaluates the submitted corrective actions and confirms acceptance thereof. The implementation of the corrective actions will be verified in the next audit. 						
Opportunities for	Aspects that would lead to management system optimization with respect to a requirement of the standard.						
improvement (I):	(Basic requirement for the identification and recording of opportunities for improvement is that the requirements of the standard regarding the process element have been fulfilled but that there are still areas for potential improvement of system effectiveness and efficiency. Implementation by the organization is						
	recommended.)						
Positive aspects (P):	Positive aspects of the management system meriting special mention						

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All elements of the standard in each clause of the standard were found to be "in conformity/effective" except for those elements of the standard for which this action list includes nonconformities or minor nonconformities.

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Action List

The following table shall be used for all findings recorded by the audit team during an audit (certification, change, repeat, sample, special or surveillance)

Nonconformities:

Claus e no.	Process	s Findings		Results of root cause analysis*	Intended correction and corrective action (CA)*	Evaluation of CA (to be completed by auditor)		
		Description (to be completed by auditor)	Type NC/M iN	(to be completed by client in case of NC and MiN)	(incl. due dates and responsible) (to be completed by client)	Date		Evidence
6.2	Preventiv e Maintena nce	Finding: It was noted that the unit has still no set quality objective targets that will measure its performance and to be monitored on a periodic basis. Supporting audit evidence: No evidence presented at the time of audit.	MiN	Detailed quality objectives that capture performance of all other functional units have not been established yet.	Immediate solution for the correction of the finding: Revise charter of quality objectives to include performance target and accomplishment of preventive maintenance of infrastructures, vehicles, machineries and equipment. 01/21 V. Lopez Corrective Action to eliminate the cause: Ensure that the established objectives shall met through accomplishment of preventive maintenance activities.			

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Claus e no.	Process	cess Findings		Findings Results of root caus analysis*		Results of root cause analysis*	Intended correction and corrective action (CA)*	Evaluation of CA (to be completed by auditor)		
		Description (to be completed by	Туре		(incl. due dates and responsible)	Date	• •			
		auditor)	NC/M	(to be completed by			Accept	• • •		
			iN	client in case of NC and	(to be completed by		ed	findings)***		
				MiN)	client)		(A)**	- 3-7		
8.5.1	CBED	Finding: It was noted that the form to be used for the recording of monitoring of beneficiaries of the PAIWI Family Module as prescribed in the system is no longer being implemented, thus, the parameters to be monitored such as BCS and milk production is not evident that these are being done consistently. Likewise, it could not also be established that the monitoring is being done monthly as also specified in the Quality Plan. Supporting audit evidence: Field Monitoring sheet. PCCUSM- CBQF-05 was last used October 14, 2019, the form to be used during monthly monitoring as described in CBED Quality Control Plan, PCCUSM-CBPL-01, Rev. 4, effective Nov. 4, 2019 Only the conception was seen monitored in the logbook.	MiN	PCCUSM-CBQF-05 is intended for the Regional Impact Zone. It should have been declared obsolete. It was not reflected in the Quality Plan that the said form is not anymore used. PCCUSM-CBQF-07 is logbook where the data collected from the PAIWI module shall be reflected. Monthly monitoring could not be done due to wide area of coverage.	Immediate solution for the correction of the finding: Use only one registered document as field monitoring form 12/10/20 – N. Ibrahim/R. Bermudez Corrective Action to eliminate the cause: Revise the quality Plan indicating that PCCUSM-CBQF-07 will be the form to be used Immediate solution for the correction of the finding: Revise the quality control plan indicating that monitoring will be done quarterly. Corrective Action to eliminate the cause: Regular monitoring will be conducted as planned and counter- checking that monitoring has been accomplished through monthly submission of reports.					

Note 1: Root cause analysis and corrective action are only mandatory for NC or MiN findings.

* see "Guideline for Corrective Actions Acceptance" at end of document for further assistance

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** The intended corrections and implemented corrective actions have to be verified. The Auditor shall evaluate "Effective" (E) in the case of NC and "Accepted" in the case of corrections for MiN findings, if appropriate.

*** A NC requires a re-audit, during which the corrective actions are evaluated for effectiveness.

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Opportunities for improvement and positive aspects:

Claus e no.	Process	Findings	Action for optimization (optional for client to fill out)			
		Description (to be completed by auditor)	Type I/P	Action	Responsible	Date
7.1.3	Maintenance	Finding: To be checked during next visit the inclusion of the old gen set in the PM Plan/ Program since maintenance activities are still being done on the equipment even if it is not yet being used while awaiting for its repair.	l (actio n item)	To be included in PM Plan/Program of all equipment, continue the PM of the said equipment	V. Lopez/GSU	11/05/20
6.2	CBED	Finding: May consider to include the monitoring of beneficiaries as per schedule as one of the unit's quality objective targets.	I	Revise charter of quality objectives to include annual monitoring of targets of all CBED areas.	N.Ibrahim, R. Bermudez/CBED L. Estimo/QMR	12/15/20
9.2/ 10.2	IQA	Finding: To be checked during next visit the checking on the formulation of corrective action, ensuring that it will be systemic and wholistic in nature. Noted that the corrective actions of some findings are still correction in nature.	l (actio n item)	To coordinate with OED-IMAS to conduct follow-up training on RCA through webinar	J.Rabanal,R.Bermud ez/IQA	11/17/20

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Claus e no.	Process	Findings	Action for optimization (optional for client to fill out)			
		Description (to be completed by auditor)	Type	Action	Responsible	Date
7.5.3	DCO	Finding: To be checked during next visit the inclusion of the Calibration Certificates and Training Certificates in the Masterlist of Records, with retention periods described.	l (actio n item)	To include calibration certificates, training certificates and other externally sourced records in the Master list of Records (PCCUSM- MLQF-01)	R.Valdez/DCO	11/05/2020
9.3	QMR	Finding: May consider to expound further the description of the status of the mandatory input re the performance of external providers in the minutes of MR, case in point, as to how many suppliers were evaluated, results of evaluation and if feedback was sent to the suppliers, etc.	Ι	To be discussed during the next MR meeting	L. Estimo/QMR	01/26/2021

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General

If Minor nonconformities identified in the last audit are not closed in an acceptable manner, they must be rated as Nonconformities (reaudit required).

Information on findings management in sampling and multi-site certification

The management representative of the central office must check whether systematic corrective actions to close a root cause can be applied in a preventive manner to other affected sites. This is required for findings from internal and external audits.

In sampling certification, the TMS auditor will select and audit other sites in the next audit cycle and consequently cannot verify on site the effectiveness of the corrective actions from the last audit cycle.

Given this, during the next internal audits carried out at the sites concerned, the management representative of the central office must verify on site the effectiveness/acceptance of the corrective actions taken to address **Nonconformities**, **Minor nonconformities** and **Opportunities for improvement**, if any.

The results must be recorded and submitted to the TMS auditor at the next audit to ensure the auditor can verify the effectiveness of the corrective actions initiated.

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Guideline for Corrective Actions Acceptance

Objective: The purpose of this section is to provide a consistent set of criteria for the development, acceptance and implementation of corrective action responses. These guidelines apply to <u>all</u> standards on the basis of the ISO 17021 (i.e. QMS, EMS, AMS, ENMS). They are intended for TÜV-SÜD auditors and audited organizations to help them understand how nonconformities should be addressed.

1. Was correction to eliminate existing finding completed?

Describe corrections for NC and MiN taken under "Intended correction and corrective action". e.g.: Completed missing internal audits; Conducted supplier evaluations; Segregated nonconforming material, etc. Provide evidence that actions were planned, taken and are effective.

2. Have the appropriate root causes been identified? Consider the following:

- what caused the actual nonconformity (for NC and MiN) (occurrence of systematic failure)?
- what allowed the problem to occur without being detected internally?
- which part of the organization's processes failed to address this issue or is the organization lacking a specific process, method, etc.?
- is the nonconformity also applicable/found in other sites (in case of multi-site and sampling certification)?
- The cause shall not be a repeat or a rewording of the nonconformity statement nor of the objective evidence.
- e.g.: apply the 5-Why method for root cause analysis

3. Has a corrective action been determined for each identified root cause? Each root cause must have at least one identified corrective action that eliminates / addresses the specific cause(s) and prevents recurrence of the nonconformity. In the case of multi-sites and sampling certification, verify if the corrective action can be applied in other sites as well.

4. Has appropriate evidence been provided to verify that actions taken have been implemented and are effective?

It is the responsibility of the organization to provide evidence of internal verification of the corrective action(s), or a plan to do so. The Lead Auditor will provide due dates for submitting evidence of implementation. This could vary depending on the circumstances and standards involved.