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NAB-MALTA INFORMATION

INF001- Analysis and Extent of Cause

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 NAB-MALTA				Information			INF001
Page No.	1	of	2	Analysis and Extent of Cause			
Revision No	0						
Date	10/05/2021						


Clause 7.6.8 of the 2017 version of ISO/IEC 17011 (the standard with which all accreditation bodies must comply) has introduced a change to the NAB-MALTA assessment procedure:

*7.6.8 When nonconformities are identified, the accreditation body shall define time limits for correction and/or corrective actions to be implemented. **The accreditation body shall require the conformity assessment body to provide an analysis of the extent and cause (e.g. root cause analysis) of the nonconformities and to describe within a defined time the specific actions taken or planned to be taken to resolve the nonconformities.***

The relevant part in is in red, and the part that the NAB-MALTA is particularly interested in is in bold. Basically, NAB-MALTA assessors are instructed not to clear NCs unless CABs provide an analysis of **extent** and cause for every NC. It has been noticed that analysis of extent is not always clear in responses from CABs; some are struggling with it as they were not obliged to provide it in the past. For this reason, we are providing the following examples:

- An assessor identifies in an NC that competence records are not up to date for a lab technician for a particular test method. The laboratory should, in its response, confirm that it has checked that the out of date records did not extend to all of the other technicians (or if it did, that the records for all were brought up to date).
- An assessor identifies in an NC that a confidentiality agreement between an inspection body and one of its inspectors is deficient in some way. The inspection body should check all confidentiality agreements to determine if it was a one-off incident, or if it extended to other inspectors, and include this information in its response. If it extended to other inspectors, the response should confirm that agreements were corrected for all affected personnel, not just for the inspector identified in the NC.
- An assessor identifies in an NC that an inspector is using a piece of equipment that is out of calibration. The inspection body should check the equipment held by the other inspectors, and confirm in its response to the NAB-MALTA whether or not it was a one-off issue, or if it extended to the other inspectors.
- An assessor raises an NC because a CAB issued an accredited certificate/report for an activity that was not covered by its scope of accreditation. The CAB should check for the presence of all other similar occurrences and include this in its response to the NAB-MALTA.

For each NC, following analysis of extent, if the CAB determines that the issue is limited to only the example identified in the NC, then this should be stated in the response to the NAB-MALTA.

 NAB-MALTA				Information			INF001
Page No.	2	of	2	Analysis and Extent of Cause			
Revision No	0						
Date	10/05/2021						

Note that the above examples deal only with the extent element; analysis of cause is also required, as well as taking whatever action is necessary. But it is likely that one of the first steps to determining the cause of the issue would be to understand the extent.

Disclaimer

This information is intended for informational purposes only.