

### Management of external documentation.

In the distant past, INAB used to require organisations to keep controlled copies of INAB and other external documentation. This is no longer the case.

Conformity assessment bodies (CABs) are required to ensure that they keep informed of relevant INAB notifications maintained on the INAB Website (<http://www.inab.ie/inab-documents/>), and are also required to ensure that they keep informed of EA, ILAC and IAF publications relevant to their areas of activity. But CABs are not required to keep controlled copies of INAB documents; all that is required is that the CAB needs to identify if any changes are needed, and if they are, to have evidence that appropriate changes were made to the CAB's management system.

### Analysis of extent and cause

Clause 7.6.8 of the 2017 version of ISO 17011 prompted a change to INAB 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 highlighted in red, and the part that INAB is particularly interested in is in bold.

Basically, INAB assessors should not clear NCs unless CABs provide an analysis of extent and cause for every NC.

Recent experience has shown that analysis of extent is not clear in many responses from CABs; many are struggling with it as they were not obliged to provide it in the past. So, some examples are given here:

- 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 The laboratory should, in its response, confirm that it has checked that the out of date records did not extend to all of the other technicians (or if it did, that the records for all were brought up to date).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 a certification body and one of its auditors is deficient in some way. The CB should check all confidentiality agreements to determine if it was a one-off incident, or if it extended to other auditors, and include this information in its response. If it extended to other auditors, the response should confirm that agreements were corrected for all affected personnel, not just for the auditor 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 IB should check the equipment held by the other inspectors, and confirm in its response to INAB 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 INAB.

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 INAB.

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.

### Review of sensitive/confidential information while on assessments.

Where the assessment involves examination/review of sensitive documentation, such as competence or contractual information related to an individual, please ensure that suitable facilities are provided to ensure confidentiality. If an assessor is assigned a guide who may not be appropriately qualified to be involved in the review of certain sensitive information, please ensure that the guide is aware that the assessor should be directed to more appropriate personnel, such as HR or a more senior staff member.

Please contact your assessment manager if you would like further information.