

Management of Non-compliances

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1. Entry in DANAKs Non-compliance database

Non-compliances identified by DANAK during a visit are reported in DANAKs Non-compliance database on the customer portal. Here the observed findings as well as reference to accreditation requirements and the applicant or accredited company's own system documentation are stated.

The name of the person from DANAK who has identified the individual Non-compliance will appear.

DANAK will notify if one or more of the formulated non-compliances provide grounds for a recommendation for suspension. For assessment at laboratories, this will be stated in the visit recommendation. This will also be stated in the report sent after the assessment.

The deadline for submitting the company's response to non-compliances and documentation for non-compliance treatment is agreed at the final meeting of office and laboratory visits and will subsequently be visible in the Non-compliance database. The deadline will generally be 1 month, and a maximum of 3 months can normally be accepted. However, time limits that only relate to an applied extension will be of a voluntary nature, as the extension can only be approved after the related non-compliances have been closed. The same applies to non-compliances detected during accreditation visits. A long period of time for applications may result in a follow-up visit being carried out before accreditation.

2. Submission and assessment of non-compliance treatment

Before the expiry of the agreed deadline, the company shall have completed the 4 activities in the table below for each of the detected non-compliances. The company enters a description for each of the items in the non-compliance database and attaches relevant documentation. If, based on the review, it is not found that there is a need for correction or corrective action, the company shall explain this in its response.

| Item | Description |
|---------------------------------|---|
| Extend (including consequences) | Non-compliances are often found on the basis of limited samples, and the companies themselves must carry out a thorough investigation of the extent to assess whether there are similar non-compliances in other areas and, for example, how many cases are affected. In addition, the consequences of the non-compliance and the extent shall be investigated. |
| Correction | Correction of the matters identified in the above investigation shall be carried out. |
| Cause | An investigation shall be carried out revealing the reason for the non-compliance. |
| Corrective action | Based on the above investigation of the cause, changes shall be made to procedures, processes, training or other things to prevent the reoccurrence of the same type of non-compliance. |

Example 1:

A Non-compliance is written stating that a caliper is not calibrated as specified in the management system.

Extend: It is investigated whether there is other measuring equipment that is not calibrated, as specified in the management system. It is investigated whether the measuring equipment used has measured incorrectly and, if so, the consequences that may lead to the withdrawal of measurement reports and/or products are investigated.

Correction: All measuring equipment found during the above investigation is calibrated. Measurement reports and/or products are recalled in cases where the measuring equipment has measured significantly incorrectly.

Cause: The reason for the lack of calibration of the measuring equipment is investigated.

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Corrective action: Based on the root cause analysis, a system (procedures, data system, marking or other) is introduced to ensure, that all measuring equipment for which calibration is required is calibrated regularly.

Example 2

DANAK writes a non-compliance stating that the company has used an employee for an area where it has not been documented that the person possesses sufficient competence.

Extend: It is investigated whether there are other cases where the same employee or other employees have performed tasks for which there is no documented competence. It is also investigated whether there was a lack of competences or whether the competences were present, and it was the registration/documentation that was missing.

Correction: The company corrects the error based on the analysis of extend and consequence, i.e. it may be that the consequence was small, as all employees were competent, but the registration was missing for one or more, and it will be sufficient to obtain the missing documentation and register it. Or it may be that there was a lack of competence to such an extent that the work, cf. the analysis of extend, must also be redone by competent employees.

Cause: It is investigated what the reason is for the use of one or more employees who were not documented competent for the task. For example, the reason may be errors or deficiencies in procedures, misperception of understanding, lack of resources or incorrect requirements for updating.

Corrective action: Based on the analyses above, the company ensures (through procedures, systems, training or otherwise) that it does not happen again that there are employees with insufficient documentation of competence who perform work under the accreditation.

The company is asked to inform DANAK by email when responses to non-compliances has been entered.

DANAK assesses the received responses and submitted documentation for non-compliance treatment and closes the non-compliances when this is deemed satisfactory. DANAKs assessment of the non-compliance treatment will be available in the non-compliance database.

If there are non-compliances that are not considered satisfactorily processed, the evaluation is described in the Non-compliance database. DANAK will notify the status of non-compliances via email, from which a new deadline for response will be stated. The company must then process the non-compliance again and submit further descriptions or documentation. DANAK sets the new deadline considering the nature of the non-compliance and that non-compliances normally must be closed after approx. 3 months.

DANAK informs via email when there is a new status in the non-compliance database.

It is always the lead assessor who makes the final decision on whether a non-compliance can be closed. Where the non-compliance has been established by a technical assessor, the decision is normally made based on the recommendation of the technical assessor.

Guidelines for the use of DANAKs Non-compliance database can be found on www.danak.dk under *Extranet* in the document in Danish *Vejledning til kundeportal*.

This document is a translation. Any differences between the Danish and the English version are not intended, but in case of doubt with respect to the correctness the version in Danish should be consulted.