

# Technical Bulletin: Healthcare sector improvement action closure – root cause and extent requirements

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A trend has been noted within the Healthcare sector whereby customers provide suitable evidence to clear a specific mandatory improvement action raised, but either perform unsatisfactory investigation of the root cause, extent and impact or fail to provide any evidence for this requirement to be met. On some occasions, customers copy-and-paste the improvement action into the root cause field in the customer portal/IAR spreadsheet, which is not sufficient to demonstrate that root cause analysis has been performed.

Having no root cause or consideration of extent and impact detail does not demonstrate that, as an organisation, you have considered and addressed the underlying problems. The root cause is not the finding that is raised.

When a customer does not provide evidence of effective and appropriate cause, extent and impact analysis, UKAS is unable to close the associated mandatory finding.

As the sole national accreditation body for the United Kingdom, UKAS operates in accordance with the requirements specified in **ISO/IEC 17011 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies**.

ISO/IEC 17011:2017 clause 7.6.8 states:

“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.”

To ensure the requirements of ISO/IEC 17011:2017 clause 7.6.8 are met, UKAS requires all customers to identify and record the root cause of all mandatory findings raised by the UKAS assessment team, investigate the extent of the nonconformity and ascertain the impact of the nonconformity on other accredited activities and service users.

A number of tools are available to support effective root cause analysis, including the ‘5 Whys’ technique and Fishbone/Ishikawa diagram.

The UKAS Training Academy also offers an e-learning module on this topic [Nonconforming work, cause and extent - UKAS](#) which may be helpful to UKAS customers, both when managing their own internally-identified nonconformances and when clearing findings raised by external bodies such as UKAS.

### Example Improvement Action:

*Recent recruit JS was found to be competent in their technical role but no records of their training or authorisation could be found. Further checks on the records of 5 other recent recruits found records generally present but with omissions in some areas.*

**Acceptable response from customer** (in addition to information and documentation detailing actions taken to address the nonconformity):

- + **Cause:** Resourcing - the training manager had recently been on extended sick leave and as no deputy had been identified there was no one to ensure the procedure was being followed.
- + **Extent:** A total of 10 individuals were going through training in the period when the training manager was unavailable. Records of these have been checked and traced back. In all cases it was confirmed that training was provided, staff determined competent and verbally authorised by managers, but records were not maintained.
- + **Impact:** As staff had been authorised as competent for the work performed, there is no impact on the validity of test results or patient care.

### Unacceptable responses:

- **Cause:** Resource
- **Extent:** Limited – 10 persons
- **Impact:** None
  
- **Cause:** Resourcing Training Manager off
- **Extent:** 10 new starters over 3 months
- **Impact:** *blank*