Technical Bulletin: Healthcare IT system changes

16 September 2025

This bulletin is applicable to accredited customers within the Healthcare sector.

Many organisations are currently undergoing the formation of networks to benefit advances in technology and drive efficiency and patient safety benefits. Implementation of the same IT systems across networks has been recognised as an important foundation for an effective network. As a result, many customers have recently changed and/or upgraded their systems to bring about the benefits described above.

The UKAS significant nonconforming work reporting process has highlighted a pattern of Pathology LIMS incidents related to end-to-end verification and user acceptance testing, which have impacted patient results. While this trend has been observed in Pathology, it is possible that other disciplines or modalities, such as Radiology, could also potentially be affected.

A particular area of concern is the interface between the laboratory LIMS system and systems used by GPs to access the results. A number of issues have been identified including laboratory test results not being accessible to GPs, partial results being released and duplicate results being available. These issues shall be identified and resolved by accredited organisations before or immediately after go-live.

Useful guidance documents on this topic include

- Turner, E. & Bolton, J., 2001. Required steps for the validation of a Laboratory Information Management System. *Quality Assurance*, 9(3-4), pp.217–224.
- https://www.shotuk.org/wp-content/uploads/2024/10/LIMS-Validation-Plan

Note that these guidance documents are not authored by UKAS and do not automatically ensure compliance with accreditation requirements. Accredited services are responsible for ensuring that their verification/testing of IT systems is suitable for the service they provide, the users they provide it to and in compliance with the requirements of their accreditation standard.

As detailed in the UKAS Customer Agreement, UKAS customers shall notify UKAS as soon as practicably possible when there are any significant change to their premises, equipment, facilities, resources or working environment. This includes significant changes to IT systems, which must be notified to the Assessment Manager during the project planning stages. Due to the significant risk of patient impact during IT changes, UKAS assesses these changes as soon after go-live as possible, often with a review of planning activities before go-live (note that this process has been in place in UKAS for a number of years; there is no change to UKAS requirements or process).

Significant Nonconforming Work (SNoW) process

In November 2022 the UKAS Customer Agreement was updated to include clause 3.9, which defines the criteria regarding which significant nonconformities should be reported to UKAS.

Significant nonconformities indicate a potential failure by the customer to implement / maintain the requirements of accreditation. Reporting to UKAS enables UKAS to review the investigation undertaken by the customer to give assurance that appropriate actions have been taken and that the requirements of accreditation have been maintained.

Significant nonconformities shall be reported by the customer to their Assessment Manager as soon as practicable.