Technical Bulletin – Accreditation of medical laboratory examination/test processes delivered between multiple legal entities

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Introduction

This document outlines the UKAS assessment approach where the applicant or accredited laboratory does not directly manage all stages of the end to end process; in other words where critical parts of the pre-examination, examination/testing or post examination process are carried out by (an)other laboratory/laboratories. This includes laboratories which are a different legal entity and/or a different accreditation reference.

This document will assist laboratories in the formulation of effective policies and procedures when they are seeking accreditation for such examinations and provide assessors with support in the assessment process.

Scope

This document applies to applicant and accredited medical laboratories.

Terminology

Examination/test - to determine the value or characteristics of a property

Pre-examination processes/preanalytical phase - processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins

Post-examination processes/postanalytical phase - processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results

Testing - determination of one or more characteristics of an object of conformity assessment, according to a procedure

Policy

The overall process with roles and responsibilities shall be clearly defined, and formal agreement/contracts(s) shall be in place between the legal entities involved.

The laboratory taking responsibility for ensuring the whole process including pre/post examination/analytical stages meets the needs of the user(s) and the requirements of ISO/IEC 17025 and/or ISO 15189 shall be clearly defined.

There shall be bi-directional governance arrangements between the entities, including arrangements for sample traceability, investigating and responding to complaints or nonconforming work as relevant to the examination.
Each stage will have a defined input (sample) and output (report/result) as relevant to the process. Acceptance criteria shall be defined and implemented for ‘sample’/input and ‘result’/output for the part of the process carried out by each entity/laboratory.

Where a service accredited to either ISO 15189 or ISO/IEC 17025 is not available for a stage of the examination process (including any pre/post stages) the laboratory taking responsibility for ensuring all stages meet the users’ needs and requirements of ISO 15189 or ISO/IEC 17025 shall assure themselves of the competence of the individual laboratories involved to undertake the work.

The responsible laboratory shall demonstrate competence to carry out this review.

Contracts/formal arrangements between the parties shall include this requirement, unless the laboratories to be used are otherwise specified.

The applicant/accredited laboratory’s agreement(s) with users of their services shall include details associated with the phased examination approach.

Where relevant the input (sample type) and the expected output will be clearly defined on the schedule of accreditation.

UKAS will assess the appropriateness and effectiveness of the above arrangements.

References

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

ISO 15189 Medical laboratories - Particular requirements for quality and competence