Assessor Guidance: Assessment and Accreditation of Medical Laboratory Services Delivered Off-Site

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Definition

Off-site:	Any medical laboratory not on the hospital site at which the test was requested.
Multi-site:	Any medical laboratory operated by one legal entity and covered by a single management system that operates over multiple sites at which testing or other activities (such as phlebotomy) occur. Common terms used in medical laboratories are “networks” and “hub and spoke” models.

Introduction

As the proposals made by NHS Improvement and NHS England are developed and implemented in the English sustainability and transformation partnerships, multi-site models will become more common. UKAS recognises that, in all jurisdictions, if an organisation wishes for their laboratory accreditation to cover more than one site, the requirements of ISO 15189:2012 and TPS 51 apply. It is recognised that there are several models for service delivery, including provision of a medical laboratory service to multiple hospitals operating within a single legal entity (usually an NHS Trust, Health Board or private hospital chain) or multiple legal entities.

Whilst requirements of TPS 51 apply, given the variety of medical laboratory delivery models it is necessary to define specific considerations for assessment to ISO 15189:2012. The traditional model for the delivery of medical laboratory services has been from laboratories located within the hospital site at which the test was requested. Therefore, an assessment of the end-to-end service was facilitated as the customer/user of the medical laboratory was normally within the same entity responsible for delivering the medical laboratory service. Medical laboratory services are increasingly being delivered at alternative locations, which may or may not be the responsibility of the organisation at which the test is requested and may include private providers. Medical laboratory services may be managed by NHS organisations, Public Health England or private providers, with various arrangements for legal ownership. This has led to more complex arrangements, but end-to-end service delivery must still be considered and assessed.

General Guidance and Principles

A laboratory accredited over multiple sites can be viewed from an accreditation perspective as a single laboratory connected by very long corridors. Equally, the clinical service should be viewed from the perspective of the end-to-end services received at each individual hospital. Whether samples are tested at one site and the advisory service is delivered elsewhere should be immaterial. In this respect, it can be seen how important (and complex) it can be for a multi-site accreditation to work effectively and meet user requirements.

The generic requirements of TPS 51 apply and underpin any assessment of multi-site accreditation. Questions an assessor might ask themselves could be:

a) Is the laboratory providing a clinically-focussed end-to-end service, irrespective of the location from which the analytical phase of the testing service is being delivered?

b) Are relationships between locations and the extent of interactions documented?

c) Work transfer - are samples moved between locations for testing? Are the organisational responsibilities for maintaining the integrity of specimens clearly defined and audited?

d) Staff transfer - are staff contracted to work at a specific site, or do procedures allow for working at some or all locations within the multi-site laboratory? If there is no rotation of staff, are there varying competences and training requirements and is there an impact? Conversely, if staff are expected to work at multiple sites, are there common competence and training criteria?

e) Equipment transfer - is this documented and audited?

f) What comparability exercises have been performed between instruments offering the same scope of testing on each site? What are the associated uncertainties? Are there common IQC and EQA acceptance criteria?

g) Is there rationalised reporting? How does it work?

h) Are multi-site policies in the Quality Manual suitably defined? Is it clear who is responsible for which activities?

i) Is the quality management system developed, applied and maintained equally across all sites? For instance, are incident reporting, the audit programme, competency assessment and procedures consistent across all sites? Are non-conformities found at one site evaluated for their significance at other sites?

j) Review IT connections to ensure end to end connectivity for results reporting and flagging of new and/or unexpected results to the referring clinicians on each site.

Medical laboratories provide a clinical service and to achieve accreditation to ISO 15189 laboratories must demonstrably meet the needs of users of the service. This is regardless of whether the laboratory is on site. For instance:

a) Evidence must be provided that the Laboratory Director (or delegated alternative) relates and functions effectively with clinicians at all sites. In the instance of services provided by medical laboratories to smaller hospitals, the Laboratory Director (or delegated alternative) must demonstrate that arrangements are in place to ensure there is suitable communication with the relevant clinicians at the sending hospitals [4.1.1.4 (f,g)].

b) Transportation of samples must be included within the management system relevant to the degree of responsibility directly assumed by the laboratory (for example, monitoring of transportation), to ensure that samples arrive in a timely manner and under suitable conditions [5.4.5].

c) Laboratories must ensure that samples are traceable to an individual site [5.4.6(a)].

d) Date and time of specimen receipt must be recorded [5.4.6(d)]. Therefore, in the particular case of specimens collected at a remote hospital, the date and time of arrival at Pathology Reception must be recorded. If there is an off-site reception, receipt at both off site and on-site receptions should be recorded.

e) Reports should contain suitable interpretative comments [5.8.2(d)]. If automated reporting systems are in use, the automated systems that are established must be agreed with the users at the remote site. Arrangements must be in place for the consultants who are responsible for service delivery at the individual hospitals or services to be enabled to review all work-in-progress, laboratory results and to provide interpretative comments on laboratory results.

f) Arrangements must be in place to ensure that consultant pathologists responsible for the delivery of the medical laboratory service, including the remote sites, are able to provide input on the testing methodology in use for specimens received at their site.

g) The consultant pathologists and other senior managers at remote sites must be demonstrably part of the laboratory's Quality Management System. For example, they should be notified of performance in internal and external QA and outcome of investigations and be invited to participate in the laboratory's Management Reviews.

h) Assessment of user satisfaction must be undertaken from the perspective of each and every principal user, such that for secondary care services, analysis is undertaken at hospital level, rather than network level [4.14.3].

Reporting

Clear information and details of how the multi-site body is set up and operates (across all requirements of 15189 and the guidance in TPS 51) is needed in the Assessment and Improvement Action Report covering the aspects described above. A very simple principle being to document, in summary, what was looked at, what was found, and how/why this meets requirements.

Assessor notes are also an integral part of the assessment records and need to be retained to provide required further detail. UKAS records need to be sufficient so that we would know if changes have been made, for example, to site functions, tests performed at individual sites or how the group operates. The Assessment Report captures such information, which is then fed into a live forward planning document at UKAS. The purpose of the forward plan is for UKAS to document and record its plans to ensure the proper evaluation of the competence of the laboratory.

Clear evidence is needed in the Assessment Report that procedures supporting the above, their suitable implementation and implications (particularly for results reported) have been assessed. Procedures should cover, for example: contract review; use of common SOPs; use of common calibration standards, reporting of results from another location, customer workflows for samples that are prepared at one site and analysed in another; test transfer protocols. It may be helpful to use a heading hierarchy in the Assessment Report that enables differentiation between findings with group implications and those with just local implications. Any group support functions undertaken at specific locations (for instance batch acceptance testing), will need to be assessed and included in the Assessment Report.

Throughout assessments, the mind-set needs to be: how is this applied across the group and what are the implications for all related processes.