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Guidance for medical laboratory services provided as part of a network or multi-site organisation

Contents

Changes since last edition

This is the first edition of this publication.

1. Introduction

1.1 The traditional model for the delivery of medical laboratory services has been from laboratories located within a hospital, serving patients at that hospital and specified local GP surgeries. Therefore, an assessment of the end-to-end testing service, including sampling activities where appropriate (e.g. phlebotomy services) and the clinical/advisory service, was relatively straightforward, as the users of the laboratory service were easily identified.

1.2 Medical laboratory services are increasingly being delivered at alternative locations, such as laboratories not located on a hospital site, centralised laboratories providing services to multiple different hospitals, or technical laboratory activities being performed on different sites to the clinical advisory/reporting services. Medical laboratories might be managed by NHS organisations, private organisations, or other types of organisation, with various arrangements for legal ownership. This has led to more complex arrangements, but end-to-end service delivery, including sampling activities where appropriate, shall still be considered, documented, and assessed by UKAS. A key part of the assessment is ensuring that the assessment team understands the service delivery model including key service users, to be able to effectively assess that the clinical/advisory service arrangements are fit for purpose, understood by medical laboratory staff and service users, and clearly documented.

1.3 As pathology networks develop, multi-site models of service delivery are becoming more common. If a medical laboratory requires its accreditation to cover more than one site, the requirements of ISO 15189 and UKAS publication GEN 1 General Principles for the Assessment of Conformity Assessment Bodies by the United Kingdom Accreditation Service Appendix C apply. If a single diagnostic pathway is provided across multiple, separately accredited entities, the requirements of UKAS publication TPS 71 Accreditation of healthcare diagnostic pathways delivered between multiple UKAS customers also apply. In all cases there must be clear arrangements for meaningful engagement with clinical teams at each and every clinical hospital or other site.

1.4 Pathology networks, and other multi-site organisations offer different service delivery models. If services being provided at multiple sites want to hold a single accreditation, the services shall be managed by, and the legal responsibility of, one legal entity.

1.5 Possible service delivery and accreditation models include the following *(note, these are only examples, there might be numerous other models in practice)*.

1.5.1 Single centralised laboratory providing services, including clinical advisory services, to multiple hospitals and/or sampling sites. Single-site accreditation with laboratory, hospitals and sampling sites (as appropriate) all under the same, single legal entity.

- **Example 1:** NHS Trust/Board has 3 hospitals, H1, H2, H3. Microbiology laboratory is based in H1, and microbiology clinical staff provide their clinical/advisory services from that site. Samples might be taken at H1, H2 or H3, and any associated GP surgeries or other clinics. All samples are sent to laboratory on H1 site for processing and reporting.
- **Example 2:** private medical provider (e.g. independent hospital chain) with single laboratory but legal responsibility for multiple sampling locations.

1.5.2 Multiple laboratories providing services to multiple hospitals and/or sampling sites. Multi-site accreditation under one UKAS customer number with laboratory, hospitals and sampling sites (as appropriate) all under the same, single legal entity.

- **Example 1:** NHS Trust/Board has 3 hospitals, H1, H2, H3. The main haematology laboratory is based in H1. H2 and H3 have smaller haematology labs, offering a limited repertoire of testing (hub and spoke model). Samples might be taken at H1, H2 or H3, and any associated GP surgeries or other clinics. Samples might be sent to any of the labs for processing and reporting, either directly from the requestor, or might be sent to the H1 laboratory via the laboratories in H2 or H3. Clinical advisory services might be provided from any of the hospital sites
- **Example 2:** private medical provider has multiple regional laboratory sites. Samples are sent to the nearest laboratory for processing and reporting. There might be some centralised testing for complex or low volume test requests. Clinical advisory services might be provided from any of the laboratory sites or from a hospital site without an on-site laboratory.

1.5.3 NHS pathology network involving multiple NHS Trusts, where legal responsibility for all accredited pathology laboratories on all sites is taken by one of the participant Trusts. Might be service delivery and accreditation model 1.5.1 or 1.5.2 above. Clinical advisory services are usually (but not invariably) delivered along individual Trust lines.

1.5.4 Pathology network, where legal responsibility for accredited laboratories is retained by individual participant Trusts. Might be service delivery model 1.5.1 or 1.5.2 above. Single- or multi-site accreditation, as applicable. There shall be clear documentation regarding how the network laboratories interact, and contracts in place for medical laboratory services across the network. There shall be clarity over provision of clinical advisory services, delivery of which shall be aligned to individual hospital site needs.

1.5.5 Single laboratory performing technical aspects of testing (e.g. microbiology culture, cellular pathology slide preparation and staining), with the reporting/diagnostic activity and clinical advisory services provided from other sites, which might or might not be part of the same legal entity as the laboratory providing the technical service, and therefore might or might not be accredited under the same UKAS customer number. Note that the requirements of UKAS publication TPS 71 will be applicable if a single diagnostic pathway (i.e. technical activities and associated reporting/clinical advisory service) is delivered across multiple UKAS customers.

1.6 Whilst requirements of GEN 1 Appendix C apply, given the variety of medical laboratory delivery and accreditation models, UKAS has written this guidance to support both laboratory management personnel in implementing ISO 15189, and UKAS assessors in assessing multisite organisations and pathology networks.

2. General guidance and principles

2.1 A pathology service involving multiple sites (from the same or different legal entities) can be viewed from an accreditation perspective as a single laboratory connected by very long corridors. The clinical advisory service should be viewed from the perspective of the service user; whether samples are tested at one site and the advisory service is delivered elsewhere is immaterial to the service user, as long as provision of accredited advisory services is available to the service user wherever they are located.

2.2 Particular attention should be paid to situations where large “hub” laboratories provide services to a number of smaller “spoke” laboratories which in turn might provide services to clinical services based at further spoke sites. Testing might be performed at the “hub” laboratory, with accredited clinical advice provided by personnel based at any of the sites. Personnel based at any of the sites covered by the accreditation should be engaged with the testing site, in accordance with UKAS publication TPS 71.

2.3 In this respect, it can be seen how important and complex it can be for a multi-site pathology service, and any associated accreditation, to work effectively and meet user requirements.

2.4 The requirements of GEN 1 Appendix C apply and underpin any management and assessment of multi-site accreditation. Where a group of separately accredited laboratories/advisory services work together to provide a pathology service, whether this is a formal pathology network or not, the principles of GEN 1 can still be applied, but the differing activities and responsibilities of the different legal entities shall be considered.

2.5 UKAS assessments are planned using a risk-based approach. Risks that are considered when planning the assessment approach and duration include, but are not limited to, the following:

a) Scope of activities under accreditation, and the impact any non-accredited activities might have on the accredited activities

b) Accreditation history including length of accreditation and any significant and/or recurring nonconformities

c) Number of laboratory/sampling/reporting sites and the geographical distribution of those sites, including how the different sites interact, technically (e.g. transfer of samples between sites), managerially (e.g. how the management team monitors performance on all sites), and in the manner by which clinical advisory services are provided, to include integration into individual hospitals’ clinical services

d) Frequency of service changes including key staff and addition/removal of tests

2.6 Medical laboratories provide a clinical service. To achieve accreditation to ISO 15189, laboratories shall demonstrably meet the needs of patients and other users of the service, irrespective of the service delivery model provided. Requirements to be considered by laboratory management personnel in implementing ISO 15189, and UKAS assessors in assessing multisite organisations and pathology networks include the following. *Numbers in square brackets refer to the relevant clause(s) of ISO 15189:2022.*

a) [5.3.1] What evidence is available to demonstrate that the pathology service provides a clinically focused end-to-end service, irrespective of the location from which the technical and reporting/advisory phases of the service are being delivered? How are all the staff

who provide clinical advisory services, wherever located, involved in ensuring the end-to-end service is clinically appropriate and meets patient needs?

b) [5.4.1] Are relationships between locations, and the extent of interactions, clear and documented?

c) [6.1, 8.1.3, 8.9] Do the clinical/advisory staff (i.e. medical pathology staff, clinical scientists, Biomedical Scientists in a clinical role) work on the same site as the laboratory or are they based on a different site(s)? If they mainly work on a different site to the laboratory, is there evidence that they are fully integrated within laboratory activities, even if those activities are provided by a different legal entity (note that the requirements of UKAS publication TPS 71 will apply in this situation), e.g. input into SOP development and review (including reporting protocols), participation in EQA performance review, participation in management reviews, input into complaint investigations, input into review of test repertoire and service developments, input into clinical risk identification and management.

d) [7.2.5] Is transportation of samples included within the management system relevant to the degree of responsibility directly assumed by the laboratory (for example, monitoring of transportation, provision of transport instructions), to ensure that samples arrive in a timely manner and under suitable conditions? This includes transport from the sampling site to the laboratory, and any laboratory-laboratory transport undertaken within a network. Are the organisational responsibilities for maintaining the integrity of specimens clearly defined and audited?

e) [6.2] Staff transfer - are staff contracted to work at a specific site, or do procedures allow for working at some or all locations within a multi-site laboratory? This includes all grades and types of staff, including laboratory support staff, Biomedical Scientists, Clinical Scientists, medical consultants, administrative staff, quality-focused staff, and any other staff involved in testing/reporting activities. Are appropriate competency assessments in place for all staff whether they work on one site or multiple?

f) [6.6.3] Reagent management - is acceptance testing performed at one site, then reagents transferred to a different site? Or is acceptance testing performed on the site at which the reagents are used? If reagents are transferred between sites post-acceptance testing, how is their suitability confirmed at the site of use?

g) [7.3.7.4] 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 processes and acceptance criteria? If not, is there justification for this?

h) [5.3.2] Are multi-site-working policies suitably defined? Is it clear who is responsible for which activities? Are the requirements of GEN 1 and TPS 71, where applicable, met?

i) [8.1.1] Is the management system developed, applied and maintained equally across all sites? For instance, are incident reporting processes, the audit programme, competency assessment and procedures consistent across all sites? Are nonconformities found at one site evaluated for their significance at other sites?

j) [7.6.3, 7.4.1.3] Is there end-to-end IT connectivity for results reporting and flagging of new and/or unexpected results to the referring clinicians on each site?

k) [5.2.2] Evidence shall be available to demonstrate 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 off-site requestors (including those at other hospitals, GP surgeries, or other clinics/sampling sites) the Laboratory Director (or

delegated alternative) shall demonstrate that arrangements are in place to ensure there is suitable two-way communication with the relevant clinicians at the requesting sites.

l) [7.2.2] User information shall clearly identify which tests are performed at which sites, to ensure requestors send samples to the correct sites without undue delay.

m) [7.2.3.1] Laboratories shall ensure unequivocal traceability of the patient to the request, sample, and, when applicable, anatomical site.

n) [7.2.6.1] Date and time of specimen receipt shall be recorded, when relevant. Therefore, in the particular case of specimens collected at a non-laboratory site, the date and time of arrival at pathology reception should be recorded. If there is a hub-and-spoke model, with samples initially being delivered to the spoke site, for onwards transport to the hub laboratory, receipt at both hub and spoke site receptions (sometimes two levels of spoke) should be recorded where possible and appropriate. If this is not enabled by the LIMS, are alternative systems put into place and sufficient audits undertaken to demonstrate compliance?

o) [7.4.1.6, 7.4.1.2, 5.3.3, 8.2.5] Reports should contain suitable interpretative comments, where relevant. If automated reporting systems are in use, the automated systems that are established shall be agreed with all users on all sites. Staff providing the accredited reporting service, whether based centrally or at local sites, shall be able to view the totality of the work process and be enabled to provide clinical comments pertinent to the clinical services provided from each site. For some disciplines, access to the original request form (physical or a scanned copy) is important as clinical information is handwritten/drawn on the form which is not necessarily transcribed into the LIMS system.

p) [7.4.1.2, 5.3.3,8.2.5] Where laboratory technical services and clinical advisory services are provided from different sites (as part of the same or different legal entities), arrangements shall be in place for the staff who provide the accredited clinical advisory service to be able to review all work-in-progress and laboratory results, in order to be able to provide an effective advisory service to services users on any site, as needed. As above, for some disciplines, access to the original request form (physical or a scanned copy) is important as clinical information is handwritten/drawn on the form which is not necessarily transcribed into the LIMS system.

q) [8.1.3, 8.2.5] All staff at all accredited sites shall be demonstrably part of the laboratory's management system. For example, they shall have awareness of, and access to, management system policies, procedures and forms, be notified of performance in internal QC and external QA including outcome of investigations (where applicable) and be invited to participate in the laboratory's management reviews (where applicable).

r) [8.6.2] Assessment of user satisfaction should be undertaken from the perspective of each and every principal user. User satisfaction data should enable laboratory services to implement appropriate corrective action or service improvement, should any be required. Accredited services should consider how they will analyse and present the data, to ensure they can identify the source site of feedback for any required action or proposed improvement.

s) [7.8] Business continuity plans shall be in place and take into consideration situations where technical and/or clinical advisory services are limited.

3. Engagement with clinical users outside the accredited service/network

3.1 In some instances, clinical advice is given by personnel outside of the accredited service. For example, a hospital without an in-house laboratory might hold a contract with an external, accredited laboratory for the testing and initial reporting/clinical advice, but the local microbiologists might review some/all of the results to offer further advice as they will be familiar with the patient, clinical context, local antimicrobial stewardship and other relevant local information. The advice given by the local microbiologists is outside of accreditation, so the accredited laboratory has no control over, or record of, the advice given. However, ISO 15189:2022 clause 4.3 h) requires accredited laboratories to make available relevant information to health service providers acting on behalf of the patients. The definition of "relevant information" will vary depending on the clinical situation but could include details of analytical methods, information about additional testing not included in the report (e.g. all antibiotics tested, not just those reported), accreditation status of individual tests, measurement uncertainty of specific tests, or any performance concerns about tests (e.g. EQA concerns).

4. UKAS reporting and records

4.1 Clear information and details regarding the service delivery model, laboratory/sampling sites, and service users (across all requirements of 15189, the guidance in GEN 1 Appendix C, and the requirements of UKAS publication TPS 71 shall be included in the assessment report and improvement action report covering the aspects described above.

4.2 It is the responsibility of each accredited organisation to inform UKAS of changes to service delivery models at the earliest opportunity, to enable UKAS to assess the changes for assurance of ongoing compliance with ISO 15189.

4.3 UKAS records shall be sufficiently clear to easily identify service changes which might not have been notified to UKAS, including changes 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 assessment programme held internally by UKAS. The purpose of the assessment programme is for UKAS to document and record its plans to ensure effective evaluation of the competence of the laboratory.