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UKAS policy on accreditation of medical laboratories performing genomic tests

Note: UKAS is developing a plan to support accredited medical laboratory services impacted by this policy. The plan will be published following completion of the consultation period of this policy and publication of the final version.

Medical laboratory services are requested not to submit extension to scope applications in response to this policy until the final version and implementation plan are published.

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Contents

Changes since last edition

This is the first edition of this publication.

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1. Introduction

1.1 Genomic testing services in the UK are provided via numerous different service delivery models, ranging from traditional pathology disciplines (e.g. histopathology/microbiology) offering a small scope of molecular testing on all-in-one/ cartridge-based platforms, through to Genomic Laboratory Hubs offering large, complex, ever-changing testing scopes.

1.2 Histocompatibility and Immunogenetics (H&I) services use a lot of the same technical methods as genomic services; this policy is not aimed specifically at H&I services, but the accreditation principles described can be applied to H&I labs wanting a flexible scope of accreditation.

1.3 This policy details UKAS's risk-based approach to accreditation of genomic services, to ensure accreditation remains appropriate, timely and responsive to user needs. A number of genomic testing methods are listed as examples in this policy; not all current and future methods can be listed, but the principles outlined in this policy are able to be applied to all methods and scenarios.

1.4 UKAS accreditation is based on the demonstration of competence and conformity to the relevant accreditation standard. For medical laboratory services, this includes both the technical competence to perform tests, and the competence to interpret/report those results and offer appropriate clinical advice to users and/or patients.

1.5 Due to the use and application of the same equipment, analytical techniques/measurement principles and technical competence to identify different mutations or disorders, many of which are unidentified at the start of the diagnostic process, there is inherently a benefit for a genomics service to be accredited using a flexible scope approach. The level of flexibility and the boundaries associated with that flexibility will be defined by each service, in conjunction with UKAS. This publication shall be read in conjunction with UKAS publication GEN 4 *UKAS policy and general guidance for the implementation and management of flexible scopes of accreditation*.

1.6 In line with UKAS publication GEN 4, the implementation and effectiveness of a medical laboratory's management system in controlling its flexible scope of accreditation will be assessed as part of the normal accreditation assessment cycle. Sufficient time will be allowed at assessments to assess the continuing competence of the medical laboratory service to operate its flexible scope. The assessment effort required for these assessment activities will depend upon the approach taken, the activities involved, risks associated with activities, and the number and complexity of examination methods included.

1.7 Accreditation will be awarded for a flexible scope where the medical laboratory service can demonstrate to UKAS that it is competent to manage a flexible scope approach to accreditation. Where a medical laboratory service is unable to maintain its competence or demonstrate compliance with the requirements (for example, if records of changes made and evidence of their associated validation/verification processes are not available, incomplete, or do not demonstrate compliance with the relevant accreditation standard), the flexible scope will be rescinded. Depending on the circumstances the medical laboratory service may be able to revert to a fixed scope of accreditation. In this case the UKAS schedule will be updated to list the individual gene mutations/disorders which the medical laboratory service has demonstrated that it is competent to identify and, where applicable, interpret. Any additions to the list of individual gene mutations/disorders will require an extension to scope (ETS) application to be submitted. Accreditation will remain fixed (i.e. not flexible) until confidence in the competence of the medical laboratory service to manage the flexible scope process is demonstrated. This will require an extension to scope application from the medical laboratory service.

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2. General information

2.1 Some genomics equipment can be used for multiple different analysis techniques or measurement principles. For example, a Rotor-Gene can perform PCR and High Resolution Melt analysis, and an ABI genetic analyser can be used for fragment analysis, Sanger Sequencing or qualitative and quantitative Realtime PCR. In order for a medical laboratory service to be able to claim accreditation for the different analytical techniques/measurement principles available on a single platform, each technique and principle requires specific accreditation application, successful assessment and inclusion on the UKAS schedule of accreditation.

2.2 It is important to note that the same molecular variant can be detected using different measurement principles/technology. For example, the *JAK2 V617F* mutation can be detected using Sanger Sequencing, Next Generation Sequencing (NGS), Pyrosequencing and ddPCR. In order for a medical laboratory service to be able to claim accreditation for the different measurement principles, each principle requires specific accreditation application, successful assessment and inclusion on the UKAS schedule of accreditation. For example, a change in detection of *JAK2 V617F* from pyrosequencing to ddPCR would require an extension to scope (ETS) application to be submitted and successfully assessed before accreditation could be claimed, unless the ddPCR methodology was already accredited under a flexible scope, with boundaries that would include *JAK2 V617F*.

2.3 When an accredited medical laboratory service introduces new equipment (see 2.4), new measurement principles, and/or new sample types, these will require an extension to scope application to be submitted.

2.4 Like for like changes in instrumentation can be made without submission of an ETS application, as long as the processes for which the medical laboratory service was originally accredited remains unchanged. “Like for like” changes include replacement of equipment of the same make and model, or implementation of additional equipment identical to already-accredited equipment (i.e. to increase capacity). This principle also applies when medical laboratory services install new equipment from the same manufacturer, which has undergone a minor upgrade. UKAS should be consulted during the change control process, to confirm whether or not an ETS application is required. Medical laboratory services can claim accreditation for tests run on new instrumentation which does not require an ETS application as soon as the verification process is successfully completed in accordance with their internal procedures. Services shall inform UKAS of the change, which will be assessed at the next annual assessment, and may require additional assessment effort.

2.5 Regarding the level of flexibility in the scope of accreditation, and the associated boundaries, it is the responsibility of each accredited medical laboratory service to define their own boundaries of competence, which UKAS will then assess. UKAS will assess both the technical competence and the clinical/interpretive competence of each medical laboratory service.

For example, a medical laboratory service might be accredited, under a flexible scope, for detection and identification of nucleic acid sequence variants using Next Generation Sequencing in haematological disorders. Where common equipment, kits/panels and methods are used, accreditation can be claimed for detection and identification of any nucleic acid sequence variant, using NGS, in haematological disorders. If the medical laboratory service wants to extend its accreditation to use the same equipment, kits/panels and methods to detect nucleic acid sequence variants in solid tumour disorders, this would require an ETS application to be submitted, as UKAS has no previous evidence of the medical laboratory service’s competence to interpret and provide clinical advice on solid tumour disorders. The ETS assessment would likely focus on the interpretation and clinical advice requirements of the standard, whilst not completely omitting assessment of the technical service.

2.6 Section 3 of this document gives examples of examination methods/measurement principles, and the flexible scope accreditation boundaries which could be considered by medical laboratory services. Where named examples of equipment or analysers are included in this policy, they have been added to support reader clarity and understanding. Lists of equipment or analysers are not exhaustive, nor do they imply UKAS endorsement of the named examples.

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3. Guidance – Test method examples

3.1 Cartridge-based (sample to result)

Examples include:

- Biocartis Idylla
- Cepheid GeneXpert

These tests and platforms are straightforward to use, requiring direct addition of patient samples to a cartridge for analysis. The test kits are specific for point mutations, fusions, or microsatellite instability (for example), and understanding of differing clinical utility, interpretation and provision of advisory services must be assessed to ensure competence in these areas is demonstrated. These platforms are unlikely to benefit from a flexible scope unless regular changes (e.g. regular addition of cartridges or targets) to the test repertoire are expected.

3.2 Services using non-cartridge-based equipment - Pre-examination

Pre-examination phases can include (note this list is not exhaustive):

i. Sample preparation steps e.g. centrifugation to remove plasma, extraction of specific lineages (e.g. CD3+, CB19+), cell harvest and processing, FFPE block cutting, micro/macro dissection

ii. DNA and RNA extraction and reverse transcription of RNA to cDNA for use in down-stream processes

iii. Quantification of DNA/RNA/cDNA (this is generally not reported and used solely for the purposes of QC prior to downstream processes)

iv. Cell culture for Karyotyping

Although these processes do not produce a reportable result, they are critical to the testing process and must be captured in the accreditation assessment and records. These steps (if applicable to the medical laboratory service) shall appear on the schedule of accreditation, including whether they are manual, automated, or both.

Kits used for DNA/RNA extraction or preparatory steps are validated by the manufacturers to be used on specific sample types and with specific equipment, therefore a fixed scope of accreditation is usually appropriate.

If a medical laboratory service is accredited for DNA/RNA extraction from a specific sample type using a specific kit and specific equipment, then wishes to extend their accreditation to include DNA/RNA extraction from a different sample type, using the accredited kit and equipment, and the sample type has been validated by the manufacturer (i.e. is listed in the Instructions for Use), this will not require an Extension to Scope application, but the service must notify UKAS of the change. The verification of DNA/RNA extraction from the new sample type will be assessed by UKAS, either as extra assessment effort added to the annual surveillance/reassessment visit, or as a stand-alone chargeable extra assessment. The accredited service can only claim accreditation for this change when the assessment is completed, and the published UKAS schedule of accreditation has been updated.

Where a new DNA/RNA extraction kit is introduced, with no change to the chemistry or sample type, but with a minor change to the methodology (e.g. volume change/timings differences between Maxi and Mini kits), this will not require an Extension to Scope application, but the service must notify UKAS of the change. Medical laboratory services can claim accreditation for the new kit as soon as the verification process is complete and signed off. The new kit will be assessed at the next annual assessment and may require additional assessment effort.

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For equipment and methods which are multifaceted (i.e. can be used for DNA and RNA extraction), services which are accredited for DNA extraction on a specific platform must apply for an extension to scope if they want to include RNA extraction in their accredited scope (and vice versa).

If a service wishes to extend its accreditation to include sample types not validated by the manufacturer, new kits and/or new equipment, these will all require submission of an Extension to Scope application.

If a service regularly changes its sample types, kits and/or equipment, a flexible scope of accreditation for pre-examination processes may be suitable.

3.3 Services using non-cartridge-based equipment - Analysis & interpretation

3.3.1 Sanger sequencing

Sanger sequencing methodology involves detection and identification of nucleic acid sequence variants (e.g. SNVs, small indels and breakpoints) across a range of disorders, with common equipment, methods and technical competence.

UKAS will assess the competence of a medical laboratory service to perform Sanger sequencing, including primer design and optimisation, and result interpretation/analysis, using the same equipment, kits/ in-house methodology (with optimisation of extension) and chemistry (same Mg, Taq, dNTPs), and analysis software across a range of mutation types and disorders, as applicable to their testing and clinical advisory service. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for detection of any sequence variant type in specific disorder types (e.g. haematological, solid tumour), including confirmatory testing whereby primer optimisation (as above) is required, using the accredited equipment, kits/in-house methodology and chemistry, and versioned software. If a medical laboratory service cannot demonstrate competence and compliance across this range, individual mutations/disorders will be assessed and listed on the UKAS schedule as a fixed scope.

Due to the non-targeted nature of confirmatory testing and the need for primer design and optimisation with method verification/validation, it can only be accredited as a flexible scope. If a medical laboratory service cannot demonstrate competence to manage a flexible scope, confirmatory testing will not be accredited.

If a medical laboratory service wishes to extend its accreditation to include different in-house methodology/chemistry, equipment, kits, or targets out with its accredited scope of competence for clinical advisory services, an extension to scope application will be required.

3.3.2 Pyrosequencing

Most medical laboratory services utilise pyrosequencing for 2 purposes – sequencing or determining methylation status (e.g. in MGMT).

For use in sequencing the accreditation approach as discussed above for Sanger sequencing applies.

Methylation tends to be kit-based or in-house method based. The same assessment and accreditation principles apply as for sequencing assessment and accreditation. Flexible scope accreditation may be appropriate if the same methodology, kit and/or equipment is used to detect methylation status of different genes, in line with manufacturer's validation, and there are frequent changes to the targets being assessed for methylation status by the accredited medical laboratory service.

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3.3.3 Fragment length analysis

The same assessment and accreditation principles apply as for sequencing assessment and accreditation i.e. UKAS will assess a medical laboratory service's competence to perform fragment length analysis, including result interpretation/analysis, using the same equipment, kits/ in-house methodology and chemistry, and analysis software across a range of mutation types and disorders, as applicable to their testing and clinical advisory service. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for detection of any mutation or mutation type (including CNV or methylation status by MLPA kit) in specific rare disease, cancer or acquired disorder using the accredited equipment, kits/in-house methodology and chemistry, and versioned software. If a medical laboratory service cannot demonstrate competence and compliance across this range, individual mutations/disorders will be assessed and listed on the UKAS schedule.

Fragment length analysis involves a number of different methodologies, kits and chemistries. Several examples are listed below. Where a specific example is not listed, the principles of this policy will still apply.

3.3.4 PCR with resolution by Gel Electrophoresis

The assessment and accreditation principles apply as listed above. If methodology and chemistry are identical for analysis for a regularly changing set of targets (e.g. SNV, indel, fusion) then flexible scope accreditation might be appropriate. However, if new methodology (chemistry, PCR conditions, etc) is introduced, then an ETS is required to add targets to scope.

3.3.5 MLPA for detection of CNVs and large rearrangements

Multiplex Ligation-dependent Probe Amplification (MLPA) methodology involves determination of gene copy number across a range of mutations/disorders, using commercial kits with common equipment (normally genetic analysers with fragment analysis capability). The assessment and accreditation principles apply as listed above.

3.3.6 Methylation Specific Multiplex Ligation-dependent Probe Amplification (MS-MLPA)

The same principles apply for accreditation of MS-MLPA as accreditation of MLPA for the detection of CNVs and large rearrangements.

If a medical laboratory service is accredited for MLPA for the detection of CNVs and large rearrangements, it cannot be assumed that that the service is automatically competent to perform, and be accredited for, MS-MLPA. An extension to scope assessment will be needed if the service is only accredited for the detection of CNVs and large rearrangements but wants to also be accredited for MS-MLPA, and vice versa.

3.3.7 Quantitative Fluorescence PCR (QF-PCR)

This method is used to determine change in gene copy numbers across a range of mutations/ types of disorders (e.g. prenatal, post-natal), using commercial equipment and software.

The assessment and accreditation principles apply as listed above for all types of fragment length analysis. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for determination of copy number changes in named types of disorders (e.g. prenatal, post-natal). If a medical laboratory service cannot demonstrate competence and compliance across this range, individual disorders will be listed on the UKAS schedule.

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3.3.8 Capillary Electrophoresis - fragment size

Commercial kits

There is a vast range of kits being used by medical laboratory services for the purposes of PCR and resolution by genetic analyser.

The assessment and accreditation principles apply as listed above for all types of fragment length analysis. Each kit, and target type it detects, must be assessed and documented on the schedule of accreditation. Examples include detection of fragment length size, deletions, known mutations, repeat expansions, or linkage markers, CF analysis, triplet repeats, microsatellite instability, Short Tandem Repeats (STRs, including chimerism analysis).

For kit-based tests resolved using capillary electrophoresis, UKAS will assess the competence of the medical laboratory service to use these kits and analyse outcomes. If a medical laboratory service can demonstrate competence and compliance, it may be accredited for detection of any specific target types offered by the kit in any disorder using the accredited equipment, kits, methodology and chemistry, and versioned software (flexible scope). If a medical laboratory service cannot demonstrate competence and compliance across this range, competence to detect specific targets will be assessed and listed on the UKAS schedule.

If a medical laboratory service changes a kit (and therefore chemistry) or adds a new kit with new target type, and wishes to claim accreditation for the new kit, an ETS application and assessment will be required.

In-house methodology

Most in-house methods are likely to be validated for a single target type, which will be listed on the UKAS schedule of accreditation.

As most in-house methods are likely to be validated for a single target type, it is likely an ETS application will be needed if a medical laboratory service changes their in-house methodology.

Due to the non-targeted nature of confirmatory testing and the need for primer design and optimisation with method verification/validation, it can only be accredited as a flexible scope. If a medical laboratory service cannot demonstrate competence to manage a flexible scope, confirmatory testing will not be accredited.

3.3.9 Southern Blotting for detection of large gene rearrangements

UKAS will assess the competence of a medical laboratory service to perform southern blotting, including primer design and interpretation/analysis, using the same equipment, kits/ in-house methodology and chemistry and analysis software, across a range of large gene rearrangements, as applicable to their service and clinical advisory services. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for detection of any rearrangement, using the accredited equipment, kits/in-house methodology and chemistry and versioned software. If a medical laboratory service cannot demonstrate competence and compliance across this range, individual mutations/disorders will be assessed and listed on the UKAS schedule.

If a medical laboratory service wishes to extend its accreditation to include different in-house methodology/chemistry, equipment, kits, or targets out with its accredited scope of competence for clinical advisory services, an extension to scope application will be required.

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3.3.10 Qualitative Real Time PCR and Qualitative Reverse Transcriptase PCR (RTPCR)

For example, *JAK2 V617F* SNP detection, *BCR-ABL1* fusion detection.

Commercial kits

For kit-based tests resolved using real-time analysers:

UKAS will assess the competence of the medical laboratory service to use these kits and analyse outcomes. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for detection of any mutation, using the accredited equipment, kits/methodology and chemistry and versioned software. If a medical laboratory service cannot demonstrate competence and compliance across this range, individual mutations/disorders will be assessed and listed on the UKAS schedule. This will require additional assessment effort and associated charges.

If a medical laboratory service changes a kit (and therefore chemistry) or adds a new kit with new target type or target type not previously assessed (requiring different methodology to be adopted), and wishes to claim accreditation for the new kit, an ETS application and assessment will be required.

In-house methodology

Most in-house methods are likely to be validated for a single target or target type, which will be listed on the UKAS Schedule of Accreditation. UKAS will assess the competence of a medical laboratory service to perform the in-house method, including primer design, interpretation/analysis, and clinical advisory services.

As most in-house methods are likely to be validated for a single target type, it is likely that any changes will require different primer conditions and different methodology, meaning an ETS application will be needed if a medical laboratory service wants to include the new method in their accredited scope.

3.3.11 Quantitative Real Time PCR

For example, quantification of *BCR-ABL1*, *PML-RARA* gene fusions for purposes of MRD.

The assessment and accreditation approach as detailed for Qualitative Real Time PCR and Qualitative Reverse Transcriptase PCR (RTPCR) applies.

3.3.12 Droplet Digital PCR

The assessment and accreditation approach as detailed for Qualitative Real Time PCR and Qualitative Reverse Transcriptase PCR (RTPCR) applies where known targets are being identified.

Due to the non-targeted nature of confirmatory testing and the need for primer design and optimisation with method verification/validation, it can only be accredited as a flexible scope. If a medical laboratory service cannot demonstrate competence to manage a flexible scope, confirmatory testing will not be accredited.

3.3.13 High resolution melt analysis/melt analysis

The assessment and accreditation approach as detailed for Qualitative Real Time PCR and Qualitative Reverse Transcriptase PCR (RTPCR) applies.

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3.3.14 Next Generation Sequencing (NGS)

Next Generation Sequencing (NGS) methodology involves detection and identification of nucleic acid sequence variants (e.g. SNVs, small indels and breakpoints) across a range of types of acquired disorders and rare diseases, with common equipment, kits/panels, methods and technical competence.

UKAS will assess the competence of a medical laboratory service to perform NGS, including interpretation/analysis, using the same equipment, library preparation and enrichment methodology, and software/bioinformatics pipeline across a range of mutations and disorders, as applicable to their service. If a medical laboratory service can demonstrate competence and compliance (including panel design and verification), it will be flexibly accredited for detection of any sequence variant in named types of disorders, using the accredited equipment, kits/panels and software/bioinformatics pipeline.

If a medical laboratory service cannot demonstrate competence and compliance across this range, individual mutations/disorders will be assessed and listed on the UKAS schedule. Library preparation, enrichment method and sequencer must all be documented on the Schedule of Accreditation for fixed scopes of accreditation.

If a medical laboratory service wishes to extend its accreditation to include different in-house methodology/chemistry, equipment, kits, or targets out with its accredited scope of competence for clinical advisory services, an extension to scope application will be required.

3.3.15 Arrays

Array methodologies involve detection and identification of changes to gene copy number alterations or methylation status across a range of types of disorders (e.g. prenatal, haem/onc, solid tumour) with common equipment, kits, methods and technical competence.

UKAS will assess the competence of a medical laboratory service to perform array testing, including interpretation/analysis, using the same kits/CHIPS and equipment across a range of types of disorder, as applicable to their service. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for determination of copy number changes/methylation status in named types of disorders. If a medical laboratory service cannot demonstrate competence and compliance across this range, individual disorders will be listed on the UKAS schedule.

If a medical laboratory service wishes to extend its accreditation to include different in-house methodology/chemistry, equipment, kits, or targets out with its accredited scope of competence for clinical advisory services, an extension to scope application will be required.

3.3.16 G-banding/Karyotyping

G-banding/Karyotyping methodologies involve detection and identification of chromosomal aberrations or rearrangements across a range of types of disorders (e.g. prenatal, loss of pregnancy, haem/onc, solid tumour) with common equipment, kits, methods and technical competence.

There is minimal flexibility in cell culture and harvesting techniques and equipment.

UKAS will assess the competence of a medical laboratory service to perform G-banding/Karyotyping, including interpretation/analysis, using the same kits and equipment across a range of types of disorder, as applicable to their service. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for determination of copy number changes in named types of disorders. If a medical laboratory service cannot demonstrate competence and compliance across this range, individual disorders will be listed on the UKAS schedule.

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If a medical laboratory service wishes to extend its accreditation to include different in-house methodology/chemistry, equipment, kits, or targets out with its accredited scope of competence for clinical advisory services, an extension to scope application will be required.

3.3.17 Fluorescence in situ hybridisation (FISH)

FISH testing involves detection and identification of chromosomal aberrations or rearrangements across a range of types of disorders (e.g. haematological malignancy, breast disorders, lung disorders) with common equipment, kits, methods and technical competence.

UKAS will assess the competence of a medical laboratory service to perform FISH testing, including knowledge of probe-type application (break apart, fusion) and interpretation/analysis, using the same kits, probe types and equipment across a range of types of disorder, as applicable to their service. If a medical laboratory service can demonstrate competence and compliance, it will be flexibly accredited for determination of variant detection using these defined probe types. If a medical laboratory service cannot demonstrate competence and compliance across this range, individual targets, probes and disorders will be listed on the UKAS Schedule.

FISH is usually performed on either Formalin-Fixed Paraffin-Embedded (FFPE) samples or liquid samples. Medical laboratories accredited for FISH on only one of these sample types will need to submit an ETS application if they want to include the other sample type in their accredited scope.

If a medical laboratory service wishes to extend its accreditation to include different in-house methodology/chemistry, equipment, kits, or targets out with its accredited scope of competence for clinical advisory services, an extension to scope application will be required.

3.3.18 Bioinformatics pipelines

Each bioinformatics pipelines can be used to interpret different genetic sequences to identify a range of disorders.

UKAS will assess the competence of a medical laboratory service to manage and use commercial pipelines, as well as developing pipelines in-house, where applicable. The UKAS schedule will list the name of each pipeline and indicate whether it is a commercial or in-house-developed pipeline.

The version number of each pipeline will not usually be listed on the UKAS schedule (although there may be some occasions where this is necessary), and version changes to pipelines will not usually require an extension to scope unless the scope of the pipeline significantly changes. However, medical laboratory services must validate/verify any changes between each version. These records will be assessed by UKAS during the annual assessments.

Other externally controlled software (i.e. not only bioinformatics pipelines) is used by some genomics laboratories (e.g. the Heidelberg Classifier software for classification of brain tumours). Accreditation of these pieces of software will be dealt with on a case-by-case basis, but the general principles of accreditation and ISO 15189 always apply i.e. that the accredited medical laboratory service must validate and/or verify the functioning of the software and be able to demonstrate to UKAS that they have control over / awareness of changes made to the externally managed software.

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