Management of Flexible Scope of Accreditation

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Author Rachel Carling/Kayleigh Davis

Authorised by Fiona Denham

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1. Introduction

1.1 Purpose and Scope

Historically, accreditation was defined in very precise terms and presented as a fixed scope in the schedule of accreditation; this provided an accurate and unambiguous range of conformity assessment activities covered by a Conformity Assessment Body (CAB) accreditation. However, over time this became considered as restrictive in that it did not readily enable new or modified activities to be added to a CAB's scope[1], even where competence had already been demonstrated in associated activities. Although applications for an extension to scope could be made at any time throughout the assessment cycle, the timescales involved for the subsequent assessment and accreditation may prevent the CAB responding with agility.

Flexible scopes of accreditation provide a mechanism to allow a CAB to undertake new or modified activities within its scope of accreditation, even though the specific conformity assessment activities may not be explicitly stated on its schedule of accreditation. The degree of flexibility awarded will vary between technical disciplines and conformity assessment activities dependant on the risk associated with the activities.

Accreditation of a flexible scope places more responsibility onto the CAB itself for demonstrating that valid, fit-for-purpose processes/activities are undertaken **competently, impartially, and consistently and comply with the relevant conformity assessment body standard**. However, this does not mean that a CAB can undertake any activity that is requested of it by a user and claim that it is accredited. The bounds within which the scope is flexible must be clearly defined, with the CAB demonstrating to UKAS that it has the competence to work within the full range of its flexible scope, as well as having suitable resources. These boundaries will be dependent on the accreditation maintained, but could include flexibility in specific component(s) of an accredited activity: (a) area of activity, products, parameters, product/process/service standards, certifications, materials, schemes, sample types (b) range of activity, tests/examinations, technical/clinical disciplines, clustering of scope IAF codes (or part thereof) (c) methods, procedures, parameters, equipment, measurement, extent of technical/clinical area, specification (d) type of activities undertaken at a location.

Prior to granting a flexible scope of accreditation, UKAS will consider a number of factors, including:

- degree of understanding by the CAB of the rules and procedures for implementing and managing a flexible scope
- performance and stability of the CAB's management system, including design, implementation and robustness of procedures related to flexible scopes
- complexity of the conformity assessment activities • requirements of related schemes • extent of flexibility requested
- reputational risks for UKAS, CAB and market
- impact on independence & impartiality
- retention of technical personnel within CAB responsible for the activities relating to the flexible scope
- knowledge of the CAB and its compliance to the relevant standards and activities
- stakeholder/regulatory expectations
- extent of controls proposed for managing a flexible scope

This document describes the processes by which Biochemical Sciences, Synnovis Analytics (UKAS accreditation reference 9093), will apply for, and maintain, a management system capable of controlling a flexible scope of accreditation within the bounds of ISO15189:2022 standards.

1.2 Responsibilities

The review and update of this policy is the responsibility of the Director of Biochemical Sciences. Details of responsibilities of individuals for different aspects of this policy is listed throughout this document.

1.3 Definitions

Term	Definition
Scope of accreditation	Conformity assessment activities for which a body holds accreditation.
Fixed scope	Clearly defined description of the specific conformity assessment activities for which the body holds accreditation.
Flexible scope	The scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body.
Conformity Assessment Body (CAB)	A body (legal entity) that performs conformity assessment activities and that can be the object of accreditation.
Conformity assessment activity	An activity that demonstrates specific requirements are fulfilled. This can include testing, examination, inspection, certification and verification.
Object of conformity assessment	Any material, product, installation, process, system, person, claim or body to which conformity assessment is applied.
Schedule of accreditation	The document that UKAS issues, accompanying the certification of accreditation, to define the scope of accreditation awarded.
Conformity assessment body standard	The authoritative documents that form the basis for UKAS accreditation.

2. Health and Safety

Not applicable.

3. Conformity Assessment Body (CAB)

The CAB is Biochemical Sciences, Synnovis. Biochemical Sciences comprises of four services: Immunosuppressive Drug Monitoring, Inherited Metabolic Disease, Newborn Screening and Precision Medicine.

Biochemical Sciences operates from laboratories based at:

Synnovis Analytics, Friars Bridge Court, 41-43 Blackfriars Road, London.

Institute of Liver studies, Cheyne wing, King's College Hospital, Denmark Hill, Camberwell, London.

The CAB is responsible and accountable for all tests that are managed under the flexible scope of accreditation, which applies to the locations listed above. The CAB will ensure that all processes align with the quality management system in accordance with the department's accreditation to ISO15189:2022.

The CAB must demonstrate competency, impartiality and consistency, and comply with ISO15189 and UKAS GEN-1 principles to maintain a flexible scope of accreditation[2].

See Biochemical Sciences Quality Manual (SLM-QM-1) for further details.

Post-relocation to the new laboratories at Blackfriars in 2025, Biochemical Sciences applied to retain flexible scope of accreditation for mass spectrometry under 9093 and extend the bounds to cover the Blackfriars Hub.

Given the ongoing Transformation and the staged implementation of a common operational and quality framework, it was felt that adopting a phased approach would strengthen the credibility of this application and demonstrate controlled, evidence-based change management.

As such, although extending the boundaries of the flexible scope of accreditation to cover any eligible test provided by the Biochemical Sciences laboratories (9093) at Blackfriars Hub remains the longer-term goal, it was prudent to adopt a more conservative approach whilst the laboratories embed the recent changes.

Therefore, after careful consideration, an application to extend the flexible scope to cover the Blackfriars site was made, and at the same time, a clause was included to limit the boundaries of the flexible scope to tests provided by just four of the laboratories in Biochemical Sciences: Precision Medicine, Newborn Screening Immunosuppresive Drug Monitoring and Inherited Metabolic Disease. These laboratories already operate with well-defined clinical and scientific leadership structures that support the management of the current FS of accreditation. Validated MS-based workflows and competency frameworks are embedded, as it the quality culture.

4. Bounds of flexible scope of accreditation

The flexible scope applies only to **mass spectrometry (MS)** based techniques in which Biochemical Sciences has established, and evidenced, competence in developing and performing (see section 1).

The flexible scope does not cover new analytical principles which Biochemical Sciences has no prior experience in performing.

Flexible scope provides a basis for ensuring tests which have been transferred to an alternative analytical instrument remain within the scope of accreditation during the transfer, subject to processes described in this document.

It also applies to new tests developed using the same technology or new analytes added to existing assays.

This flexibility can only apply to tests utilising technologies which have previously been successfully validated and introduced within the department in line with ISO15189 (2012 or 2022) and have successfully been accredited within the scope of the standard.

For a test to be successfully accredited under the flexible scope, the process must be documented and controlled to ensure a full audit trail. Only those activities and locations listed under the flexible scope will be covered.

4.1 Activities covered

The flexible scope covers areas where the department has established expertise and a track record of successfully establishing methods which meet the IS015189 standard and have previously been granted accreditation by UKAS.

Flexible scope only covers tests falling into the following categories:

- New analytes not previously measured within Biochemical Sciences
- Analytes detectable during analysis using established assays but not previously quantified/reported
- Analytes already measured and reported within Biochemical Sciences, but which have been transferred to a different mass spectrometer
- Analytes already measured within the department but measured in a different matrix i.e. serum, blood, urine etc.

Flexible scope only covers the following MS technologies:

- Single quadrupole mass spectrometry (MS)
- Triple quadrupole mass spectrometry (MS/MS)

with the associated front-end technologies

- Flow injection analysis (FIA)
- Liquid chromatography (LC)
- Ultra and high-performance liquid chromatography (UHPLC and HPLC)
- Gas chromatography (GC)
- Automated sample preparation technologies

4.2 Locations

The flexible scope covers established and/or new tests that are provided by Biochemical Sciences from laboratories based on1st Floor, Blackfriars Hub, Synnovis. At the time this document was produced, flexible scope was also in place for the satellite Immunosuppressant Drug Monitoring lab, Cheyne Wing, Kings College Hospital and it is acknowledged that once this service re-locates to Bessemer Wing, the flexible scope will no longer apply to Cheyne wing.

4.3 Objects covered (i.e. sample matrices)

The flexible scope only covers the following sample matrices:

- Human serum/plasma
- Human whole blood
- Human dried blood (dried blood collected onto filter paper or with a dried blood collection device)
- Human urine
- Human cerebrospinal fluid

4.4 Limitations of the flexible scope of accreditation

Only tests utilising MS and associated technologies previously validated within Biochemical Sciences and accredited to ISO15189 may be accredited under the flexible scope.

For example, tests can only be accredited under flexible scope if they include established mass spectrometry-based techniques (MS and MS/MS) hence techniques such as time of flight (TOF) analysis or accelerator mass spectrometry are not within the bounds of the flexible scope. Likewise, tests provided by Biochemical Sciences from a different site, e.g. Bessemer Wing, Denmark Hill, are not covered, and tests provided by a different section of the laboratory also based on Floor 1, Blackfriars Hub are not covered.

5. Management of tests brought under flexible scope of accreditation

To bring a test under flexible scope, Biochemical Sciences must be able to demonstrate competence, impartiality and conformity with the key requirements of the process. In view of this, the process to bring a test under flexible scope has been designed to ensure active management and appropriate authorisation of each of the key stages thus establishing an effective audit trail. The process also includes assessment of risk, evidence that all personnel involved in the process are competent, a dual layer of approval to ensure independence and impartiality and a built-in evaluation/follow up process.

The process is co-ordinated via a bespoke change control record (CCR) template, available on the QPulse CAPA module. The individual stages of the change control template are detailed below.

Personnel managing the change control must be signed off as competent against the Review and Authorisation of Validation within Flexible Scope Competency Assessment, RCHEM-TFORM7 (previously BioSGST-SLMM-CAF-45).

5.1 Commissioning of a new test

As flexible scope may be applied to new tests developed using the technology, or new analytes added to existing assays, the first stage in the CCR relates to the commissioning of a new test. Refer to Synnovis new test procedure for full details.

5.2 Risk assessment

On completion and approval of new test commissioning via the Synnovis new test process, introduction of the new test will be risk assessed using CCR Assessment Form PATH-Q-FORM28, which is incorporated as an action within the CCR template. All risks identified must be mitigated or be able to be managed locally before test development/validation begins. Authorisation to progress will be approved by the Quality Manager and Director of Service. A copy of the completed risk assessment should be attached to the CCR.

5.3 Action Plan

The action plan is designed to help capture the tasks required for the successful introduction of a new test, identify the member of staff responsible and track progress in line with the target completion date. It also provides a useful audit trail retrospectively. Actions included under this section will be specific to the requirements of the test in question, however, they must include any remedial and corrective actions identified because of the overarching risk assessment performed (see section 5.2).

As a general guide, some aspects to consider include:

- Requirement for any additional risk assessments
- Storage of equipment, reagents and consumables
- Preparation and storage of stock, calibration or control materials
- LIMS requirements: test configuration, worklists and outstands, report format, interpretive comment codes and end-to-end testing etc.
- Access to instruments/devices
- Access to software packages
- Specimen receipt and storage logistics
- Generation of COSHH, reagents logs and other routine assay documentation
- Generation of SOPs and training documentation (assay and reporting)
- Update of cross-referenced SOPs
- Subscription to appropriate EQA scheme(s)
- Identification and planning of staff training
- Record keeping / storage of documentation
- Contingency plan agreement in the event of downtime
- Website updates
- Communication of test go-live with relevant stakeholders

5.4 Test Validation

Development and/or validation of new tests under flexible scope must be performed by members of staff who have completed, and been signed off as competent against, the Method Validation Competency Assessment RCHEM-TFORM6, previously BioSGST-SLMM-CAF-42, and ideally, the Authorisation of Validation within Flexible Scope Competency Assessment RCHEM-TFORM7 (previously BioSGST-SLMM-CAF-45).

Validation of new tests will include successful completion of the Method Validation Plan Template SLM-QF-164, the Method Validation Report Template SLM-QF-158 and the Method Validation Acceptance Form SLM-QF-8. The method validation report requires formal sign off as part of test authorisation (section 7, SLM-QF-158)

5.5 Authorisation of Test Validation

The Director of Biochemical Sciences is responsible for authorisation of test validation under flexible scope. The exception to this would be in the event that the Director has personally contributed to the validation process and could no longer be considered independent/impartial. In this situation, the test validation will be independently authorised by a Consultant Scientist (BMS or CS) who has completed RCHEM-TFORM7 (previously BioSGST-SLMM-CAF-45).

5.6 Flexible Scope Audit

Once test validation has been authorised, the test will be audited against the flexible scope criteria using the Flexible Scope Audit Checklist SLM-QF-144.

Section 1 of the audit will be performed by a Consultant Scientist, Principal Scientist, Advanced Practitioner or Operations Manager who has been **independent** of the validation process.

Section 2 will be completed by the Quality Manager (QM) after the test has been approved for accreditation. Section 2 of the audit is to ensure that key personnel as identified within this document have been responsible for approval of the test into scope. The QM must have completed and been signed off as competent against the Flexible Scope QMS Competency RCHEM-TFORM5 (previously SLMM-CAF-55).

Should any non-conformance(s) be identified at this stage, they must be rectified and closed prior to the impartiality and independence review being performed.

5.7 Impartiality and Independence Review

Personnel accountable for the development, validation, review and authorisation of new tests under flexible scope must be impartial and acting independently, i.e. must not be involved in other key elements of the process. For example, test validation cannot be authorised by the person who has undertaken the analytical process for that validation; the pre-go live audit cannot be performed by an auditor who has been involved in the validation process or authorised the validation. This will be documented in the flexible scope audit conducted.

Prior to final authorisation of the test into flexible scope accreditation, the audit report will be independently assessed alongside the authorised test validation, by the Chief Scientific Officer (CSO) and Senior Quality Manager (SQM). Both parties must be signed off as competent against the relevant flexible scope competency: RCHEM-TFORM7 (previously BioSGST-SLMM-CAF-45) for the CSO and RCHEM-TFORM5 (previously SLMM-CAF-55) for the SQM.

The CSO and SQM will sign the completed Method Validation Report Template SLM-QF-158 and Flexible Scope Audit Checklist SLM-QF-144 as evidence of review, prior to closing actions set within the impartiality and independence stage.

5.8 Test Authorisation into Flexible scope of accreditation

The Director of Biochemical Sciences will be responsible for final sign off and authorisation of the test into accreditation within the flexible scope. This cannot be

performed unless stages up to and including the impartiality and independence review have been formally approved and closed.

Once tests have been authorised, they are recorded via update to the Biochemical Sciences Record of Changes within Flexible Scope document SLM-QF-139. The record must also be made available on the Synnovis website. See Section 6.9 for website locations.

****** Copies of all signed documentation should be attached to the change control under Properties******

5.9 Senior Quality Manager Approval

The SQM is responsible for ensuring all stages have been closed appropriately with all the relevant information and evidence attached.

5.10 Follow-up

New tests included within the testing repertoire will have a flexible scope audit performed pre-go live (section 5.6) and a post-go live examination audit (RCHEM-FORM-15) scheduled 3-6 months after the test has been introduced.

The change control will remain open until after the post-go live audit is conducted and any non-conformance(s) are closed. The Quality Manager is responsible for final closure of the change control.

6. Ongoing management of the flexible scope of accreditation

Ensuring completion of the quality management aspects of the flexible scope is the responsibility of the Senior Quality Manager. Additional to this is scheduling audits to cover the tests included in the scope; reporting any non-conformances arising from audit, together with proposed actions to the senior management team via the monthly Quality Meeting and updating user information and UKAS, as applicable, once tests have been authorised to be included in the flexible scope as described in Section 1.

6.1 Competency and training

Competency and training of personnel who perform the analysis, interpretation and reporting of results for any test under the flexible scope of accreditation are managed in line with the departmental policies. See Training Manual (SLM-MP-51); Assay validation and verification SOP (SLM-MP-13), Quality Improvement SOP (SLM-QP-6).

6.2 Internal Quality Control

All tests under flexible scope will be subject to internal quality control (IQC) in line with the departmental IQC policy; see Quality Control procedures (SLM-QP-5) for further details.

6.3 External Quality Assessment or Alternative Approach to Performance Monitoring

All tests under flexible scope will be subject to EQA or a suitable alternative approach to performance monitoring as defined in ISO15189:2022 Clause 7.3.7.3(f), and managed in accordance with the departmental policy, RCHEM-POL-3. Refer to EQA SOPs RCHEM-HUB-IMD-SOP10 (previously SLMM-LP-25), RCHEM-HUB-PUR-SOP14 (previously SLMP-LP-50, RCHEM-HUB-NBS-SOP12 (previously SLMN-LP-23) and SLMMS-LP-07 for full details of individual schemes.

6.4 Equipment installation and acceptance

Equipment installation and acceptance testing is managed according to procedures in (SLM-MP-18) using the equipment acceptance form, RCHEM-FORM-22 (previously SLM-QF-68).

6.5 Movement to alternative locations

Biochemical Sciences flexible scope only applies to tests performed at the Blackfriars Hub, and (at the time of writing) in the Cheyne Wing at King's College Hospital. Movement of a test to a different location would not be within the bounds of flexible scope. A formal extension to scope application, and subsequent approval of the new site by UKAS would be required.

6.6 Record keeping

Records of any tests introduced under flexible scope are recorded using the flexible scope CCR on QPulse and managed in line with departmental change control (SLM-MP-13).

The record of changes within flexible scope form (SLM-QF-139) summarises the following information:

- Analyte/measurand
- Name(s) of staff who authorised the test validation
- Name(s) of staff who performed the independent review
- Date of authorisation into flexible scope
- Member of staff who authorised the test into flexible scope
- Sample matrix
- Equipment/technique
- SOP reference
- Change control record number
- Date UKAS informed of change
- Go-live date

Only tests brought under flexible scope of accreditation should be listed on form SLM-QF-139. These tests will not be listed on the fixed scope schedule of accreditation, the exception being the Newborn screening assays as this is a requirement of the national screening programme.

6.7 Audit of flexible scope process

Methods incorporated under flexible scope are audited in line with Internal Audit Procedures (PATH-Q-SOP34). Details of tests included under flexible scope, and updates on audits, are shared with management via the monthly Quality Meeting or reviewed at the Biochemical Sciences Senior Staff Meeting.

An audit of assay validation of a test accredited under flexible scope should be included in the audit schedule (see RCHEM-FORM-39).

QMS aspects of the flexible scope will be audited annually using SLM-QF-156 and will form a part of the audit schedule for the department.

6.8 Informing UKAS of changes made under flexible scope

A Flexible Scope review is scheduled quarterly on QPulse. This will be undertaken by the Quality Team, and acts as the trigger for informing UKAS of any changes to the flexible scope (modified or newly developed processes, or tests removed from flexible scope). The review record will be updated to state UKAS have been notified of changes by a member of the Quality Team. If no changes have occurred, this will also be documented on the review.

UKAS will be informed of any changes to the key personnel involved in the management of the flexible scope process (as specified in this policy) at the earliest opportunity, i.e. as soon as the change to personnel has been confirmed within Synnovis, which may be prior to the change actually occurring. The Operations Manager(s) will be responsible for informing the Quality Manager of the changes, who will in turn be responsible for updating the test list (if required) and informing the UKAS Senior Assessment Manager.

6.9 Information for Users

For tests that are accredited under flexible scope, this must be clearly stated on the report issued to the User.

The record of flexible scope (SLM-QF-139) must be kept updated on the Synnovis website, on the webpages for the laboratories covered by the flexible scope:

Inherited Metabolic Disease Laboratory at Blackfriars Hub | Synnovis

Precision Medicine Laboratory at Blackfriars Hub | Synnovis

Regional Newborn Screening Laboratory at Blackfriars Hub | Synnovis

Immunosuppressive Drug Monitoring (IDM) Service | Synnovis

This policy RCHEM-POL-1 (previously SLM-P-3) will also be available on the website in the same locations as SLM-QF-139, for service users to have access to a full description of the extent and management of the flexible scope.

6.10 Removing a test from flexible scope

UKAS will be informed of any changes to tests within the scope of accreditation.

The record of flexible scope (SLM-QF-139) must be updated and made available on the Synnovis website at http://www.synnovis.co.uk/departments-and-laboratories/biochemical-sciences.

Users will be informed of the change to accreditation via a departmental user letter. The test repertoire must also be updated on the website (complete PATH-Q-FORM23 and submit to the Quality Manager).

A CCR will be raised on QPulse to capture these types of change.

7. References and related information

1. UKAS. GEN 4 - UKAS policy and general guidance for the implementation and management of flexible scopes of accreditation. Edition 2. November 2024
2. UKAS. GEN 1 - General principles for the assessment of conformity assessment bodies by the United Kingdom accreditation service Edition 4. March 2024
3. BSI. Medical Laboratories – requirements for quality and competence (ISO15189:2022). December2022
4. EA-2/15M:2023 - EA requirements for the accreditation of flexible scopes. Rev 02. November 2023.