Management of Flexible Scope of Accreditation

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Version Number	Change Details	Date
11.0	Review in line with UKAS GEN4.	13/01/25
10.0	General update of section and addition of suggested CCR actions under 2.3.	27/08/2024
9.0	Inclusion of the MS satellite site located at DH. Review and update in-line with ISO15189:2022	23/01/2024
8.0	Update following the Synnovis Group rebrand	02/10/2022
8.0	Logo change	21/09/2022
7.0	Trust sign off not a requirement for UKAS accreditation	21/06/2022
6.0	RA incorporated as an action within the template. Inclusion of the validation template SLM-QF-158	30/03/2022

Contents

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 CAB's 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 promptly to market needs.

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 client 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 ISO-15189:2022 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 of different aspects of the 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 operates from laboratories based at:

North Wing (4th and 5th floors), St. Thomas' Hospital (STH), London

Satellite Mass Spectrometry (MS) laboratory, Kings College Hospital (KCH), London

The CAB is responsible and accountable for all tests that are managed under the flexible scope of accreditation, which applies to those 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.

4. Bounds of flexible scope of accreditation

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

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

Flexible scope is set out within the bounds of ISO/IEC 17025 and 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, and more recently, ISO15189:2022, 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 IS015189 standards 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 on the 4th and 5th floor of the St. Thomas' Hospital site and the satellite MS laboratory on the Kings College Hospital site.

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 as described in the method validation document SLM-QR-55)
- Human urine
- Human cerebrospinal fluid
- Human faeces

4.4 Limitations of the flexible scope of accreditation

Only tests utilising MS and associated technologies previously validated within Biochemical Sciences at St. Thomas' Hospital 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.

5. Management of tests being 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, stored 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, 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 BioSGST-PATH-SIT-NEWTESTGUIDE for full details).

In brief, justification of a new tests is included on the Synnovis New Test Form on ServiceNow and changes to IT are requested through the ICT requests section on ServiceNow. Suggestions for new tests are often internal and may also be received directly from clinical teams and service users. Any member of staff may make suggestions for new test ideas either by raising at their local section meeting or raising an improvement CAPA on Q-Pulse. Once approved locally by the Director of Biochemical Sciences, the test goes through the new test commissioning process via ServiceNow. The form details criteria and guidance for requesting a new test. If the test is to be offered to Trust Clinicians the new test must also be signed off by a representative of the Trust. Sign off by the Trust does not impact the accreditation process, nor does it limit the organisation from offering the test to external users. Copies of all test commissioning documentation should be attached to the change control record.

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 as a result of the overarching risk assessment performed in section 2.2.

As a general guide, some aspects to consider include:

- Requirement for any additional risk assessments
- Procurement of equipment, reagents and consumables
- 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)
- Completion of a BoM (in collaboration with Finance)
- Identification and planning of staff training
- Record keeping / storage of documentation
- Contingency plan agreement in the event of downtime
- Website updates for new test information: specimen requirements, TAT, methodology etc.
- 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 SLMM-CAF-42, and ideally, the Authorisation of Validation within Flexible Scope Competency Assessment 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 2.5) and Impartiality and independence (section 2.7).

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 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 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 GSTT Senior Quality Manager (SQM). Both parties must be signed off as competent against the relevant flexible scope competency: SLMM-CAF-45 for the CSO and 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 at http://www.Synnovis.co.uk/departments-and-laboratories/biochemical-sciences.

****** 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 vertical audit performed pre-go live (section 2.6) and an examination audit scheduled 3-6 months post go live.

The change control will remain open until after the follow up 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 Reference Services Quality Manager. This includes management of the flexible scope process at the satellite location to ensure the established flexible scope processes outlined within policy is maintained. 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 governance report; 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 Policy (SLM-MP-12); Policies for Training on Procedures (SLM-MI-13); Assay validation and verification SOP (SLM-MP-13), Quality Improvement SOP (SLM-QP-6).

As with all tests in Biochemical Sciences, only staff signed off as competent can perform assays and authorise results (see SLM-MP-22).

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

All tests under flexible scope will be subject to EQA and managed in accordance with the departmental EQA policy, SLM-QP-2. Refer to EQA SOPs SLMM-LP-25, SLMP-LP-50, SLMN-LP-23 and BioSGST-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, SLM-QF-68.

6.5 Requests, tenders and contracts

New tests set up at the specific requests of users are recorded as part of the New Tests process (see section 2.3). Usually, all requirements of clients are covered through the New Test process except in unusual circumstances e.g. clinical trial work covered under GCP guidelines. In these circumstances requirements are covered by contacts or SLAs, see Synnovis SLA policy (PATH-BD-SOP2) for further details. Clients are routinely informed if the tests performed are within the scope of accreditation.

6.6 Movement to alternative locations

The decision to change the location of a test is the responsibility of the Director of Biochemical Sciences and is recorded in the departmental senior staff meeting minutes (see SLM-MINS-71). Unlike other aspects of flexible scope, UKAS must be informed immediately if a test is to be carried out at a new location. These processes also apply to the removal of a location.

Biochemical Sciences flexible scope only applies to tests performed at the locations stated previously (4&5th Floors, St. Thomas' Hospital and Satellite MS lab, KCH). 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 site by UKAS would be required. Refer to section 3.9 if a test is no longer within the scope of accreditation.

6.7 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 procedures (SLM-MP-13).

Records of all tests/assays brought under the flexible scope of accreditation are documented using Biochemical Sciences Record of changes within flexible scope form (SLM-QF-139) which included 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

The record of changes within flexible scope (SLM-QF-139) should only list tests that are accredited under flexible scope. These tests won't be listed on the fixed scope schedule of accreditation apart from the Newborn screening assays, which are required by the national screening programme.

Any tests that are listed on the schedule under a fixed scope should not be included in the flexible scope record until they have gone through the process to be added to the flexible scope of accreditation.

6.8 Audit of flexible scope process

Methods incorporated under flexible scope are audited in line with Internal Audit Procedures (SLM-QP-4). Details of tests included under flexible scope, and updates on audits, are shared with management via the Governance Report (SLM-GR-2) 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 SLM-QF-13).

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.

6.9 Informing UKAS of changes made under flexible scope

UKAS will be informed of any changes to methods and/or scope at regular pre-defined intervals agreed with UKAS (**every three months**).

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.

6.10 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, see http://www.synnovis.co.uk/departments-and-laboratories/biochemical-sciences. This policy (SLM-P-3) will also be available on the website in the same location as SLM-QF-139, in order for service users to have access to a full description of the extent and management of the flexible scope.

6.11 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 2. July 2020
3. or the implementation and management of flexible scopes of accreditation. Edition 2. November 2024
4. BSI. Medical Laboratories – requirements for quality and competence (ISO15189:2012). November 2012 (incorporating corrigendum October 2014).
5. EA requirements for the accreditation of flexible scopes: https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-15-m.pdf