Contents

1 Introduction and Scope

SEPA has a schedule of accreditation granted by the United Kingdom Accreditation Service (UKAS) which is the official and detailed statement of the activities for which it has been granted accreditation.

SEPA's current scope of accreditation can be found on the UKAS website using the laboratory number 1327, and can be accessed here.

This procedure describes how SEPA manages any changes to its scope of accreditation. This may be for the introduction, amendment or removal of an accredited test or procedure. Changes may include the addition of a new location, test, determinand, matrix or equipment to an existing test; introduction of a new method, removal of an item or voluntary suspension from SEPA's scope of accreditation. These changes can be managed through either:

- A formal extension to scope (ETS) process submitted to UKAS

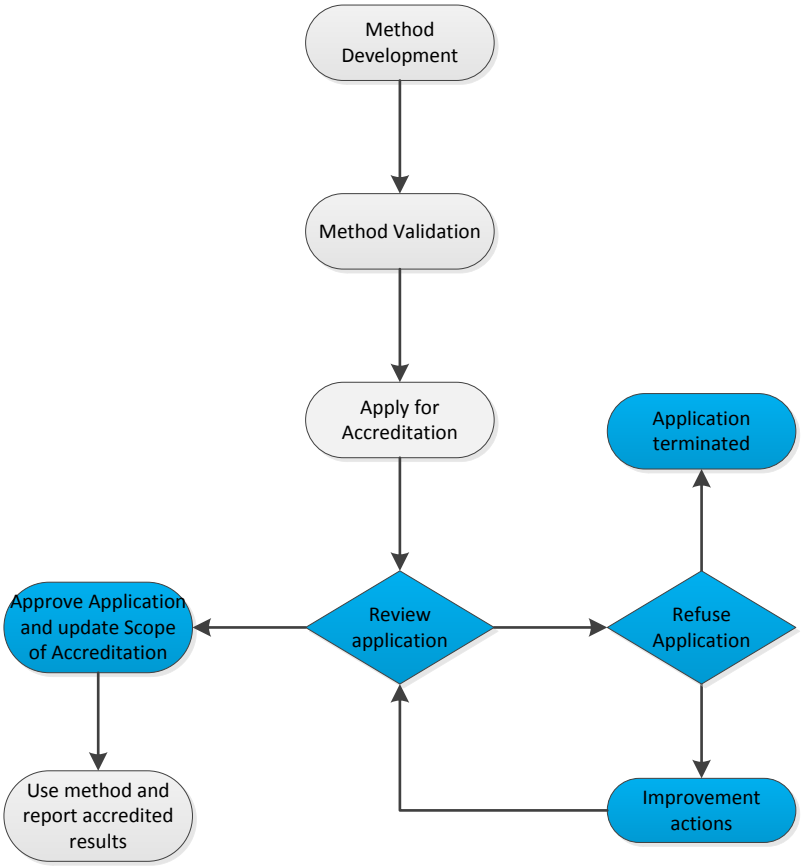
  The Fixed Scope allows the organisation to claim accreditation to ISO 17025 after the application has been reviewed and approved by UKAS (refer to section 11 where this is explained in more detail).

- The flexible ETS process which is managed by SEPA

  A Flexible Scope allows the organisation to self-approve accreditation within the parameters agreed with UKAS.

Flow diagram showing the Extension to Scope application process

Under a Fixed Scope the blue section of the flow diagram would be carried out by UKAS. With a Flexible Scope of accreditation UKAS delegate the authority to grant accreditation to the organisation. Actions and decisions in the blue boxes would be carried out by trained and authorised SEPA staff and changes to the scope of accredited tests could be made in a much shorter timeframe.



2 Purpose

This procedure deals with any changes to SEPA's scope of accreditation both to ensure that we comply with UKAS requirements and that the correct processes and approvals are followed within SEPA so that we meet all business and quality system requirements.

3 Responsibility

Full details of the roles and responsibilities of staff appointed to meet the requirements of ISO 17025 are given in BP-UKAS-01 'UKAS Organisation'. A summary of those relating specifically to changes in SEPA's scope of accreditation are given below.

3.1 Quality Manager (QM)

This role is carried out by Senior Business Consultant with responsibility for ISO 17025. This responsibility may be delegated to a suitably trained and competent member of staff.

The role will be held by the person authorised by SEPA to ensure that the management system related to quality is implemented and followed at all times.

3.2 Flexible Scope Manager (FSM)

This role is to manage the Flexible Scope process and oversee the application, review and changes to SEPA's Flexible Scope of accreditation (template BF-021).
The post will be held by the Quality Manager and they will ensure that the way Flexible Scope is applied is valid, fit-for-purpose, and is undertaken competently and consistently across all accredited areas.
They will be responsible for granting or refusing accreditation within the Flexible Scope process. Competence is recorded and stored in the Q-Pulse people module using SS-FS-TR-004 Flexible Scope Manager Competency Record.
The FSM will be responsible for communication with UKAS on any scope change that has happened using Flexible Accreditation (e.g. new Technical Assessors and additions or removals from Scope). This communication will take place in January and July each year.

3.3 Technical Assessor (TA)

This role is to support the Flexible Scope process and assess the application, review and granting of accreditation within SEPA for technical competence.
Technical Assessors will be authorised to undertake the technical evaluation and suitability of methods proposed for inclusion within the SEPA Flexible Scope of accreditation, within their area of technical competence.
They will be responsible for assessing and reporting on technical assessments to the Flexible Scope Manager and for recommending granting or refusing accreditation under Flexible Scope based on a technical review of the information.
They report to the Flexible Scope Manager for all activities and outputs relating to Flexible Scope. Competence is recorded and stored in the Q-Pulse people module using SS-FS-TR-002 Flexible Scope Technical Assessor Competency Record.
There is limited overlap between the areas of expertise and competencies of the Technical Assessors within SEPA and therefore there is limited availability for them to work as deputies for each other. If an existing Technical Assessor leaves SEPA or is unavailable, and none of the other Technical Assessors can demonstrate the required competency, then SEPA will need to use the Fixed Scope process for any changes to accreditation in that competency area (until a new Technical Assessor can be appointed).

3.4 Team Validation Lead

This role is to deliver a completed method validation for method changes. New methods and significant changes may be assigned to the Development Team (3.5).

The person in this role is required to develop new methodologies and to create method validation plans, manage the validation process, and assess whether or not the methods developed meet Customer requirements**.**
This validation output will then be prepared with all required documentation to comply with SEPA quality procedures.
They report to the management of the Unit within which validation is taking place.
Competence is recorded and stored in the Q-Pulse people module using SS-FS-TR-001 Validation Lead Competency Record. The individual records are merged and stored in Q-Pulse using SS-FS-TR-003 as a summary of available competency.
Individual Validation Lead competency records are stored in the people module of Q-Pulse under the person's name.

3.5 Development Team Validation Lead

The Chemistry Function within SEPA has a dedicated Team responsible for delivering new methods and major changes to methods. This role is to deliver a completed method validation plan for all method changes. The work to deliver the validation data for a created method may be carried out within the team owning the new method under the direction of the Development Team.
The person in this role is required to develop new methodologies and to create method validation plans, manage the validation process, and assess whether or not the methods developed meet Customer requirements**.**
This validation output will then be prepared with all required documentation to comply with SEPA quality procedures.
They report to the management of the Unit within which validation is taking place.
Competence is recorded and stored in the Q-Pulse people module using SS-FS-TR-005 Flexible Scope Development Team Validation Lead Competency Record.
Individual Development Validation Lead competency records are stored in the people module of Q-Pulse under the person's name.

4 Health and Safety

This procedure has no direct safety implications. Safety implications associated with carrying out a specific task are detailed in the relevant work procedure or test method.

5 Definitions

5.1 UKAS
United Kingdom Accreditation Service. This is the recognised body to accredit testing and analysis to the ISO17025 standard within the United Kingdom.

5.2 Fixed Scope
This is a list of tests and methods approved by UKAS to be reported as accredited to ISO 17025. This schedule is published on the UKAS website under the SEPA accreditation number 1327.

5.3 Flexible Scope
A list of tests and methods, in addition to those on the Fixed Scope, where the accreditation status is managed by SEPA within the limitations specified by UKAS on the Fixed Scope. This is stored in Q-Pulse as ISO-17025 Flexible Scope Schedule using template BF-021.

5.4 Extension to Scope (ETS)
Formal process used to apply for a change to the scope of accreditation. For a change to the Fixed Scope, the extension is assessed by UKAS. For a Flexible Scope change this assessment is carried out by authorised SEPA staff.

5.5 Method
In other organisations and literature method has been used interchangeably with the terms test and process. Method as a term is used within this document where there is a method, process or test that is to be accredited or considered for accreditation within the extension to scope process. The standard definition of method is a systematic procedure for accomplishing a task.

5.6 Test
The standard definition of a test is a procedure to establish the quality, reliability or performance of something. Within SEPA a test is normally used to describe a determination within a method.

5.7 Process
The standard definition of a process is a series of actions or steps taken in order to achieve a particular end.

6 Process Overview

Process maps have been produced to show how a change to accreditation is handled within SEPA to add methods. There is a separate flow map for removal of methods included within section 13.

- Stage 1 map shows how SEPA evaluates the requirement for accreditation changes to add methods.
- Stage 2 map shows the validation process
- Stage 3 Flexible map shows the assessment of the application for a Flexible change to accreditation
- Stage 3 Fixed map shows the assessment of the application for a Fixed Scope change to accreditation

The process maps are in Appendix 3

7 Evaluation of Extension to Scope (ETS)

Changes to the scope of accreditation may involve the addition, amendment, removal or temporary suspension of items from scope. Before any work is started on validation the request for the change must be justified and approved on the Science Accreditation Change Record (BF-213). This is a three stage process with the Unit evaluating the requirements for the change. Where an extension to scope is sought an assessment of the request by the Flexible Scope manager for the changes requested against the Flexible Scope framework will be undertaken. If the changes cannot be made within this framework the application will need to progress via an application to UKAS for a Fixed Scope change or be carried out as an unaccredited test. Where a change falls within the Flexible Scope capabilities but is more suited to being on the Fixed Scope the Flexible Scope Manager will discuss this with the Unit before processing the application.

7.1 Preparation of ETS by the Unit.

7.1.1 The request process starts with the Unit creating a new Science Accreditation Change Record (BF-213), to record the information and decisions.

7.1.2 The Unit requests from the Quality Manager an accreditation change number in the format FIX<year>-<next number in sequence> for changes to the Fixed ISO17025 scope of accreditation (e.g. FIX16-01) and FLEX<year>-<next number in sequence> for changes to the Flexible ISO 17025 scope of accreditation (e.g. FLEX16-01). The proposed changes to the current scope of accreditation (fixed or flexible) are recorded on the Accreditation Change Request Log (BF-023) by the Quality Manager.

7.1.3 Identify the Customer and ensure that the Customer agrees and approves the targets identified in 7.1.5. This step is critical and must be carried out thoroughly to ensure that the product will be able to deliver the outputs required by the Customer.

7.1.4 The first section that has to be completed is the Customer Requirements. These requirements define the work necessary and will be used to assess the application against during the process. Customer Requirements may include some or all of the following:

- Precision targets
- Bias targets
- Limit of Detection
- Limit of Quantification
- Range of method
- Accreditation
- Capacity of method
- Turnaround of results of method
- Cost of method

If the Customer is not initially able to define their requirements the Unit should work with them to create and agree a list of requirements, which will be used to set up the method.

7.1.5 Where the Customer requirements cannot be met then the agreement between the Customer and the Unit must be recorded on a BF-022 Customer Acceptance Memo detailing the original requirements and what is able to be delivered. The name of the Customer who has accepted the change in specification must be included. The record is then embedded into the Science Accreditation Change Record (BF-213).

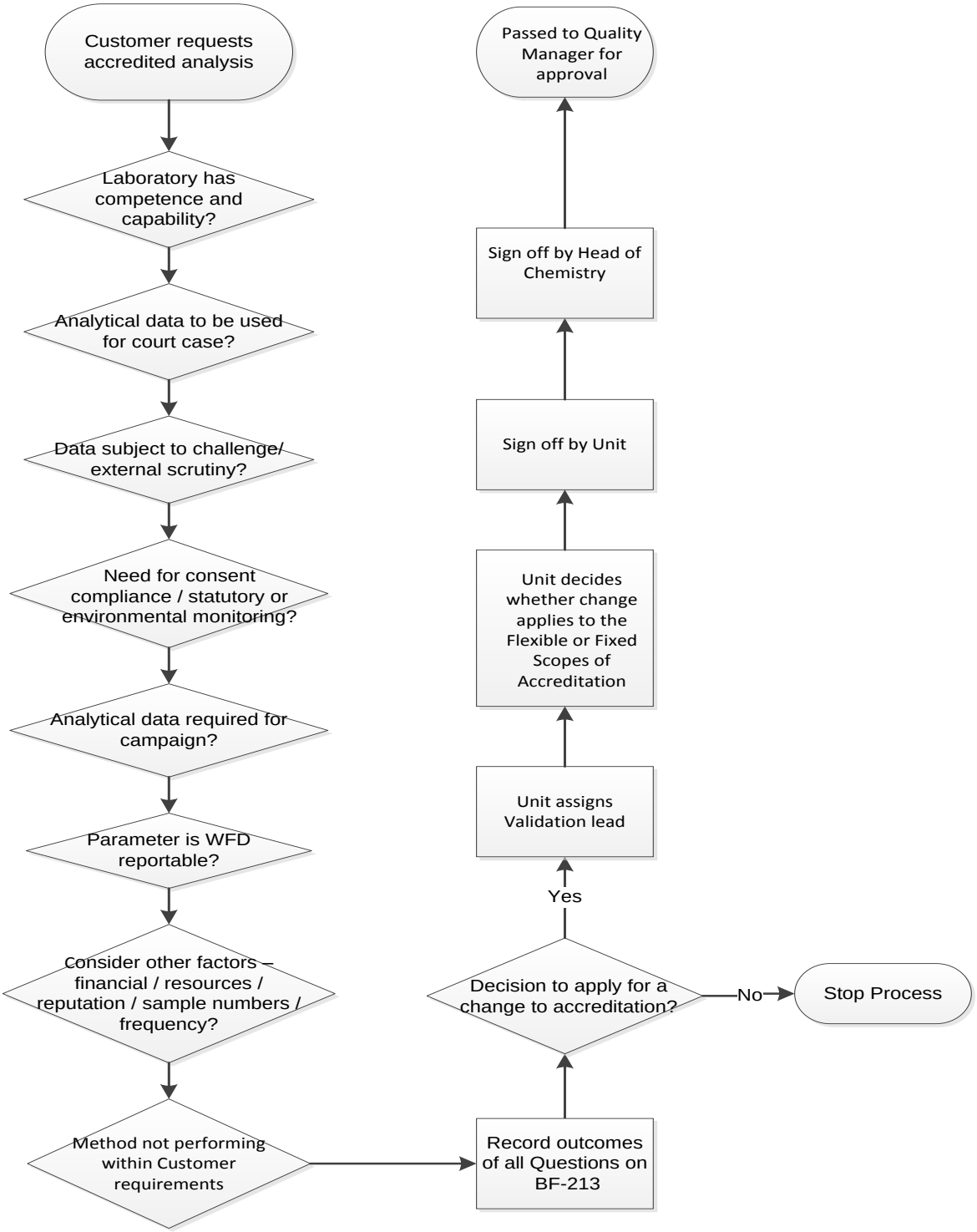
7.1.6 A brief description of the method needs to be provided on the Science Accreditation Change Record (BF-213 section B). This must include an outline of the method and methodology and describe the techniques used by the method. An example of a technique description would be: The samples are solvent extracted then cleaned up using silica filtration prior to chromatographic separation using a gas chromatography instrument fitted with a mass spectrometry detector. The method identifies and quantifies a suite of organic pesticides. This information is used to evaluate whether the method and changes proposed in 7.1.8 fall within the flexible or fixed scopes of accreditation. The description provided must be sufficiently detailed to allow evaluation of the competencies required for both the Validation Lead to conduct the work and the subsequent review by the nominated Technical Assessor. For guidance on the level of detail required and the format speak to the LQS team.

7.1.7 The requested change must clearly identify the determinands (identify types of items being tested e.g. ammonia, particle size, coliforms), matrix (see Appendix 1) and accreditation status that this change is requesting. This is recorded on the Science Accreditation Change Record (BF-213 section C).

7.1.8 The next stage is to evaluate whether the extension to scope request should progress further. This is accomplished by asking a series of questions listed in the flow diagram below. The outcome of this process should enable an informed decision to be made whether to proceed with the request or reject it as not being in the interest of the business.

The outcome of this decision process must be communicated back to the person who originated the accreditation change request, and recorded on the Science Accreditation Change Record (BF-213 section D).

Accreditation Decision Process



7.1.9 The Unit must assign a Validation Lead who has the required competencies for the proposed changes (BF-213 section E).

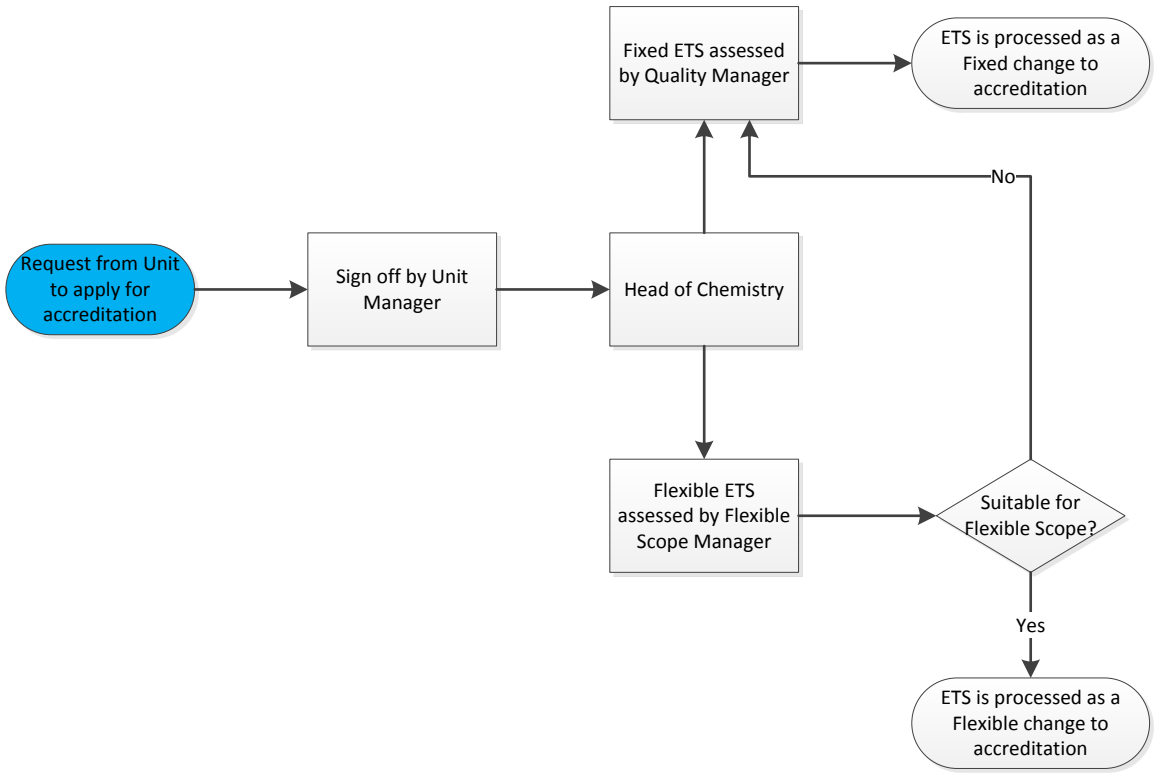
7.1.10 Each Validation Lead if selected from the analysts in a team has an individual competency record (SS-FS-TR-001) to verify competence for the work area. These individual competency records are combined into a searchable spreadsheet using template SS-FS-TR-003 to help with selection. Competence records are stored in the Q-Pulse people module.

7.1.11 For Validation Leads selected from the Development team, each member has a competency record (SS-FS-TR-005) to verify competence for the work area.

7.1.12 After the decision has been made to proceed with a request for a method to be accredited; the application goes to management for approval.

7.1.13 Process for approval

- Sign off at Unit Management level – Update BF-213 section F
- Sign off by Head of Chemistry. – Update BF-213 section F



7.2 Review of request by Quality Manager/Flexible Scope Manager

7.2.1 Inform requesting team on the outcome of the decision.

Possible outcome decisions are:

1. The change can be made under the Flexible Scope process.
2. The change is outside the limits of the Flexible Scope and an application to UKAS for a change to the Fixed Scope is recommended.
3. The change is not suitable for accreditation under ISO 17025.

7.2.1.1 Flexible Scope change (removal or addition) - option 1 above
The FSM will update the Science Accreditation Change Record (BF-213 section H) with all the decisions (and associated reasoning).

7.2.1.2 Fixed Scope change (removal, addition or temporary suspension) – option 2 above
Any changes required to the scope of accreditation must be notified to UKAS, this is done via the Quality Manager. UKAS will assess the degree of change and risk and provide guidance on the steps to be taken by the accredited laboratory. There are two types: postal assessment (desktop review), and where UKAS will require a UKAS Technical Assessor to visit the site and conduct a method witness. Each request is reviewed on an individual basis.
Discussions will then follow regarding potential timeframe and cost associated with each Extension to Scope (ETS) application. The organisation should also be aware that extending their scope of accreditation may increase the routine ongoing costs of maintaining accreditation from UKAS.
Information on the ETS process can be obtained from the UKAS website here. It provides some background and details the information required (detailed within the AC4 form for testing laboratories).

7.2.1.3 Change requests not suitable to be accredited under ISO 17025 – option 3 above
Where the changes are evaluated as not suitable to proceed with an application for accreditation or where the assessment shows there is no requirement for the change to be accredited. The change should proceed with method development and validation to show that the change meets Customer requirements.

7.2.2 For changes to the flexible scope the FSM will conduct a competence assessment for the application to ensure that the requirements of Flexible Scope accreditation are met and that the change is within the limitations of our scope. The Flexible Scope competency areas are listed on the SEPA scope (1327) on the UKAS website. If the requested change does not fall within the limitations of the Flexible Scope refer the application back to the Unit to decide if they want to proceed with a change to the Fixed Scope.

7.2.3 The request for an ETS under Flexible Scope must include an estimated time for how long the accreditation is required to remain on the Scope. It is more likely that for most Flexible Scope changes the change will be for a specific piece of work and the duration of the requirement for accreditation will be known.

7.2.4 For Flexible Scope changes a Q-Pulse audit record must be created within the Flexible Scope Audit calendar. The record should be given the same reference number identified in section 7.1.2 (the Accreditation Change Record number (e.g. FLEX 16-01)). A separate Accreditation Change Approval record should also be raised in the CAPA module. This will be used to record the approval signatures at the end of the process, and the number should be transcribed onto the BF-213 header information.

7.2.5 Approval of change request is then signed off by Quality Manager – Update BF-213 section F.

7.2.6 Complete section G of BF-213 and where the accreditation flag needs to be suspended check that the unit has requested that NEMS has been updated. The unit must notify the Customer of the change in accreditation status for any work to be reported.

7.3 Assign Technical Assessor (TA) and add their name to the audit record in the Flexible Scope audit calendar in Q-Pulse (BF-213 section I).

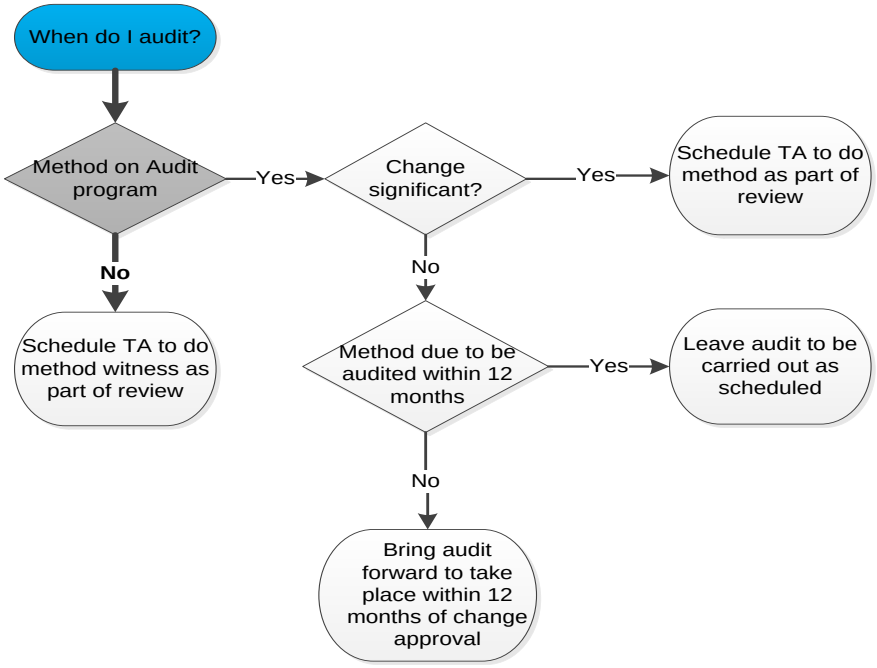
7.3.1 The Flexible Scope Manager will match the requirements of the application to one or more Technical Assessors based on their technical area of competence. Each authorised Technical Assessor has a competency recorded using form SS-FS-TR-002. Competence records are stored in the Q-Pulse people module under the individual Technical Assessors names. Where a Technical Assessor with the required competencies is not available then the application cannot proceed using the Flexible Scope and accreditation must be applied for using the Fixed Scope process.

7.3.2 Once assigned the Technical Assessor cannot plan the validation exercise or do any of the testing. They may consult and provide advice on the suitability of any validation plan created by the requesting team, but should remain as independent as possible from the validation. All review notes, findings and final recommendations made are recorded on BF-019.15 Technical Assessor Review form which once completed is uploaded and stored securely within the Q-Pulse Audit record. The Technical Assessor raises any findings as Q-Pulse CAPA actions (associated with the audit record), and the CAPA numbers are referenced in section 9 of the review form.

7.3.3 Where the change is not part of the Flexible Scope the technical assessment is carried out by someone selected by the Unit requesting the change. This should be a different person to the Validation Lead where possible to provide a robust review process of the validation plan and the data produced from the validation.

7.4 The Flexible Scope Manager will perform a risk assessment to decide when to do a method witness for all Flexible Scope changes. This hierarchy will be partly based on whether the Technical Assessor deems the change significant or not. The decision matrix will be dependent on whether the method is already included in the in-house audit program (BF-019.11).

Hierarchy for assessment:



(i) Method on existing scope or audit programme and change is not significant (e.g. extra determinand, range change, new instrument or extra matrix added), then no method witness required by the Technical Assessor and the audit is rescheduled to happen within the next twelve months.

(ii) Change is deemed significant by Technical Assessor to existing method the Technical Assessor will include a method witness as part of the evaluation.

(iii) Change to an existing method which is not on the audit programme or a new method will include a method witness as part of the evaluation.

8 Method Development

Method Development is not controlled as part of the Accreditation change process, but needs to be included in outline since it will affect timings of the review process and may lead to a revision in the requested changes which may have to be reassessed to ensure it is still within the limitations of the Flexible Scope (7.2.2).

8.1 The application for an extension to the Flexible Scope should include a defined timeline and mile stones set and be communicated to the Technical Assessor and the Flexible Scope Manager.

8.2 The accreditation change record (BF-213) will be updated with the information and a time slot will be agreed between the Unit and the Technical Assessor for the review of the validation plan.

8.3 The Unit must inform the Flexible Scope Manager if there will be any changes to the timelines agreed or if there are going to be significant changes to the method being developed.

9 Validation for an ETS

9.1 Preparation of validation plan

The Unit must review the proposed changes and assign a validation lead to prepare the validation plan. This member of staff must be competent in the applicability and limitations of the technique, and authorised by laboratory management. A combined searchable list of Validation Leads and their competencies is available to consult on Q-Pulse as document called Validation Lead using template SS-FS-TR-003.

9.1.1 Preparation of Validation plan by the Unit.

The following procedures should be used to prepare the relevant validation plan:

- ES-VALID-P-009 'Method Validation for Chemical Tests'
  For lab based Chemistry Function methods
- ES-VALID-P-010 Method Validation for Field Based Chemical Tests
  For field based Chemistry Function methods
- ES-MICRO-P-011 'Microbiological Analytical Method Validation'
  For Microbiological methods

9.1.2 When units are preparing their validation plans they must ensure that Customer Requirements have been considered and that the plans evaluate and test that the new method will meet the Customer requirements.

9.1.3 The Unit must include a validation plan outline including estimated timelines and key milestones in BF-213 section J.

9.2 Review and sign-off of validation plan

- Fixed ETS technical reviews are conducted by a Senior Specialist assigned by the Unit– Update BF-213 section K
- Flexible ETS technical reviews are conducted by the Technical Assessor assigned by the FSM– Update BF-213 section K

9.2.1 Technical review of the validation plan prepared by the Unit is to ensure that it complies with the appropriate validation procedure and will evaluate whether or not the method meets Customer Requirements.

9.2.2 The Technical Reviewer checks that the matrix names and types selected for testing comply with those listed in Appendix 1.

9.2.3 If the validation plan does not meet the requirements above the plan is passed back to the Validation Lead to make the improvements.

9.2.4 The Technical Reviewer should agree milestones and timeframes with the Validation Lead and set a date for an interim review of the validation data. The interim review will normally be scheduled at the half way point of the validation. For example, validation of a Chemistry laboratory analysis which specified an 11X2 validation the data would be reviewed when a 6X2 dataset is available. This interim check ensures that resources and time are not wasted by continuing to follow a validation plan that is not going to deliver a method that will meet Customer Requirements.

9.2.5 Request for allocation for Quality Manger time:

- For Fixed ETS the Senior Specialist notifies the QM of the timeframes so that they will know when the Extension to Scope will be sent to UKAS.
- For a Flexible ETS the Technical Assessor notifies the FSM of the agreed timeline so that time can be allocated for the Quality review.

9.3 Conduct Validation

9.3.1 Validation should be carried out following the agreed validation plan.

- Chemistry laboratory validation data should be entered into the validation spreadsheet as it is created and the first batch should be checked to ensure that all solutions and spikes being used for the validation are at the correct or expected levels.
- Microbiology validation data should be entered into spreadsheets created to comply with the Microbiology validation procedure.
- Field method validations data should be entered into spreadsheets created to comply with the Field method validation procedure.

9.4 Collation of application package

Ideally an ETS package should contain at least the following information (or justification if not provided):

- Completed AC4 form (submitted to UKAS for a Fixed ETS only)
- Documented procedure
- Training Records of relevant staff
- Method validation data and validation summary
- Uncertainty of Measurement Budgets
- Detail of the Measurement Traceability Chain
- Details of internal quality control (including control charts)
- Proficiency Testing Scheme Data
- System Suitability Checks

- Stability evaluated (if required e.g. for a new matrix or determinand)

For a Fixed application package which is to be sent to UKAS this information should be collated into a data package and filed as below, using the suggested numeric prefixes for file names to help improve clarity (unique file names can be used after the numeric as appropriate).

01 – Covering Letter

02 – AC4 form

03 – Documented Procedure

04a – Training Record – Joe Bloggs

04b – Training Record – A N Other

05 – And so on for all other documents

NOTE: In addition to the above the package should include the following documents that are not sent to UKAS.

- COSHH assessment for the method must be produced.
- NEMS change request form (NEMS-BF-004)
- Accreditation change record (BF 213)
- Technical Assessment checklist (BP 019.15) – Flexible ETS only

10 Review of Equivalent and Revised Standard Methods

10.1 Inclusion of technically equivalent standard methods

Where a request by the Customer has been made to report analysis against a standard method a formal review of the new standard method against the existing accredited method must be completed. The review must ensure that the key differences are within the bounds of the flexible scope.

10.2 Inclusion of Revised standard methods

Where a standard method that is accredited has been revised or a standard method is referenced within an accredited method a formal review must be completed. The review must ensure that the key differences are within the bounds of the flexible scope.

10.3 Formal review process

Use the Technical Assessor Standard review checklist BP-019.17 to record the formal review and outcomes. This record will include the Standards compared and the version numbers and Q-Pulse numbers for any affected methods.

The outcome of the review must be clear as to whether the new standard is equivalent to the existing standard in use. For reviews of a revised standard the outcome must be clear on whether it affects the method operation and performance. Where the standard method is significantly different, validation of the effect of the changes will need to be undertaken to ensure that the method procedure followed will meet Customer requirements if it is changed. All improvement actions will be raised in Q-Pulse to record the investigation and outcomes.

11 Review and Approval of ETS package

11.1 Unit review of application package

A final review of the validation package should be carried out by the Unit prior to the review and approvals process described in 11.2, 11.3 and 11.4. Once this is completed the Unit updates BF-213 and record their authorisation in the Authorisation record in the Q-Pulse CAPA module (number of Q-Pulse record is in the header of BF-213).

11.2 Fixed Scope change request assessment process

Once this is completed the Unit Technical reviewer updates BF-213 section L and records their authorisation in Q-Pulse (the number of the Q-Pulse record is in the header of BF-213).

Link to UKAS guidance webpage here

11.2.1 The completed package may be reviewed by the LQS team to ensure that all evidence has been supplied and is clearly documented. Any deficiencies are referred back to the Validation Lead for review.

11.2.2 The completed package is passed to the Quality Manager to complete a final review and send the package to UKAS.

11.2.3 If the changes are considered to be not significant by UKAS the application may be treated as a postal ETS. If this is the case then UKAS assesses the evidence submitted without a site visit. If UKAS consider the changes to be significant then a site audit is usually included as part of the assessment by UKAS. In both instances UKAS will normally respond within 3 months with an assessment report.

11.2.4 The accreditation is either granted immediately, or UKAS will request the completion of improvement actions. These can be clarification of evidence, additional evidence or require changes to the method to comply with ISO 17025. Any additional information will be required within 3 months and will be reviewed by the Senior Scientist, a member of the LQS Team, and the Quality Manager prior to submission to UKAS. The UKAS process allows up to two cycles of improvement action submissions, if after three rounds of actions the improvement actions are not accepted by UKAS the ETS is refused.

11.2.5 Once approved the schedule is updated by UKAS and accreditation can be claimed for any reported analysis. The Unit sends the approved NEMS change request form to the NEMS helpdesk for action (BF-213 section N).

11.2.6 The newly accredited method should be added to the in-house audit schedule (BF-019.11) to ensure that it is audited once in every four year cycle. For a new test it is advisable to schedule the audit within 12-24 months of being granted accreditation by UKAS. This should be done via a Document Change Request by the Quality Manager.

11.3 Flexible Scope change request assessment process

11.3.1 Technical Assessment of application

The Technical Assessor will review the validation data and all supporting documentation for the method change. The Technical Assessor records all their observations and findings on a single form (the Technical Assessor Review form) BF 019.15). Any improvement actions raised during the review are raised as improvement actions in Q-Pulse with the Q-Pulse reference numbers included in the form.

The review may include undertaking a method witness if this was specified in 7.4. The Technical Assessor is determining whether the method as validated is technically correct and that there is sufficient evidence that it will meet the identified Customer Requirements. The outcome of the review will be as follows:

a. Pass - send to Flexible Scope Manager.
b. Pass in part – after discussing outcome with Unit the recommendation to partially grant is sent to Flexible Scope Manager e.g. one determinand out of three determinands requested to be added as accredited.
c. Fail and need more work – discuss with Flexible Scope Manager and agree remedial work with Unit (Technical Assessor to raise Improvement Actions in Q-Pulse, as identified in the Technical Assessor Review form BF 019.15).
d. Fail completely; inform Flexible Scope Manager that the application should be refused.

If accreditation has been granted subject to clearance of Improvement Actions, a timescale should be agreed between the Unit and the Flexible Scope Manager for evidence to be submitted addressing the deficiencies. On receipt of the further evidence, reviews by the Technical assessor and Flexible Scope Manager will be carried out. Should all the actions be addressed satisfactorily accreditation will be granted. However, should this not be the case further evidence or clarification may be requested.

Once this is completed the Technical Assessor updates BF-213 section L and records their authorisation in Q-Pulse (the number of the Q-Pulse record is in the header of BF-213).

11.3.2 Assessment of compliance with ISO 17025

A review of the Improvement Actions in Q-Pulse and recommendations from the Technical Assessor on BF-019.15 checklist will be carried out by the Flexible Scope Manager.

The proposed changes to the scope of accreditation must meet the following criteria:

a. The limitations of the Flexible Scope
The limitation for changes are defined on the SEPA scope (1327) held on the UKAS website from section two onwards which lists the Flexible Scope.

b. SEPA must be able to demonstrate the competencies
Competencies are the techniques and expertise that SEPA is able to demonstrate to support the ability to make changes using a Flexible Scope. Any method change to be accredited under the Flexible Scope must have staff who are able to demonstrate the competencies up on which the method is based conducting the method development and validation of the changes.

c. Customer Requirements
The Customer Requirements will have been supplied by the Unit at the start of the application for an accreditation change. If the requirements set by the Customer have not been met by the validation exercise then either Customer permission must be obtained for operating the method with revised targets (recorded as a Customer Acceptance Memo BF-022) or accreditation will be refused.

d. Technical review
The technical assessment report is reviewed. All improvement actions are required to be addressed and the report closed before accreditation can be granted.

The outcome of the review will be as follows:

- Grant of Accreditation
- Grant of Accreditation (subject to clearance of Improvement Actions)
- Partial Grant of Accreditation
- Refusal of Accreditation

The Flexible Scope Manager will notify the Unit with the decision outcome, then update BF-213 section L and record their authorisation in Q-Pulse (number of Q-Pulse record is in the header of BF-213).

Where the outcome is that further work is required by the Unit an additional Approval of Accreditation Package table will be required to be added to BF-213 to sign off and approve the additional evidence.

11.3.3 Implementation of assessment outcome

If accreditation has been granted the FSM sends the approved NEMS change request form (NEMS-BF-004) to the NEMS helpdesk for action. The Unit will inform the customer the successful outcome of the process (BF-213 section N).

The Flexible Scope Manager arranges for the Flexible Scope of accreditation to be updated. (BF-213 section M)

12 Process Review and Audits

12.1 Flexible Scope Methods

12.1.1 The Flexible Scope Manager will ensure that auditing requirements have been met for the method and if the method was not audited as part of the evaluation process by the Technical Assessor that it is included in the SEPA method audit programme (see 7.4)

12.1.2 Audit findings will be reviewed to assess whether or not the findings raised would affect the accreditation status of the method. If they do then they must either be rectified or the accreditation is removed (13.1).

12.1.3 The Flexible Scope Process is audited annually and any audit findings raised which would affect the integrity of the management of accreditation shall be rectified and UKAS informed of the issue by the Quality Manager.

12.1.4 Management review will include an assessment of the suitability of the Flexible Scope procedure and the need for changes to the Flexible Scope of accreditation.

12.2 Fixed Scope Methods

12.2.1 The Quality Manager will arrange for the method to be added to the method witness audit programme.

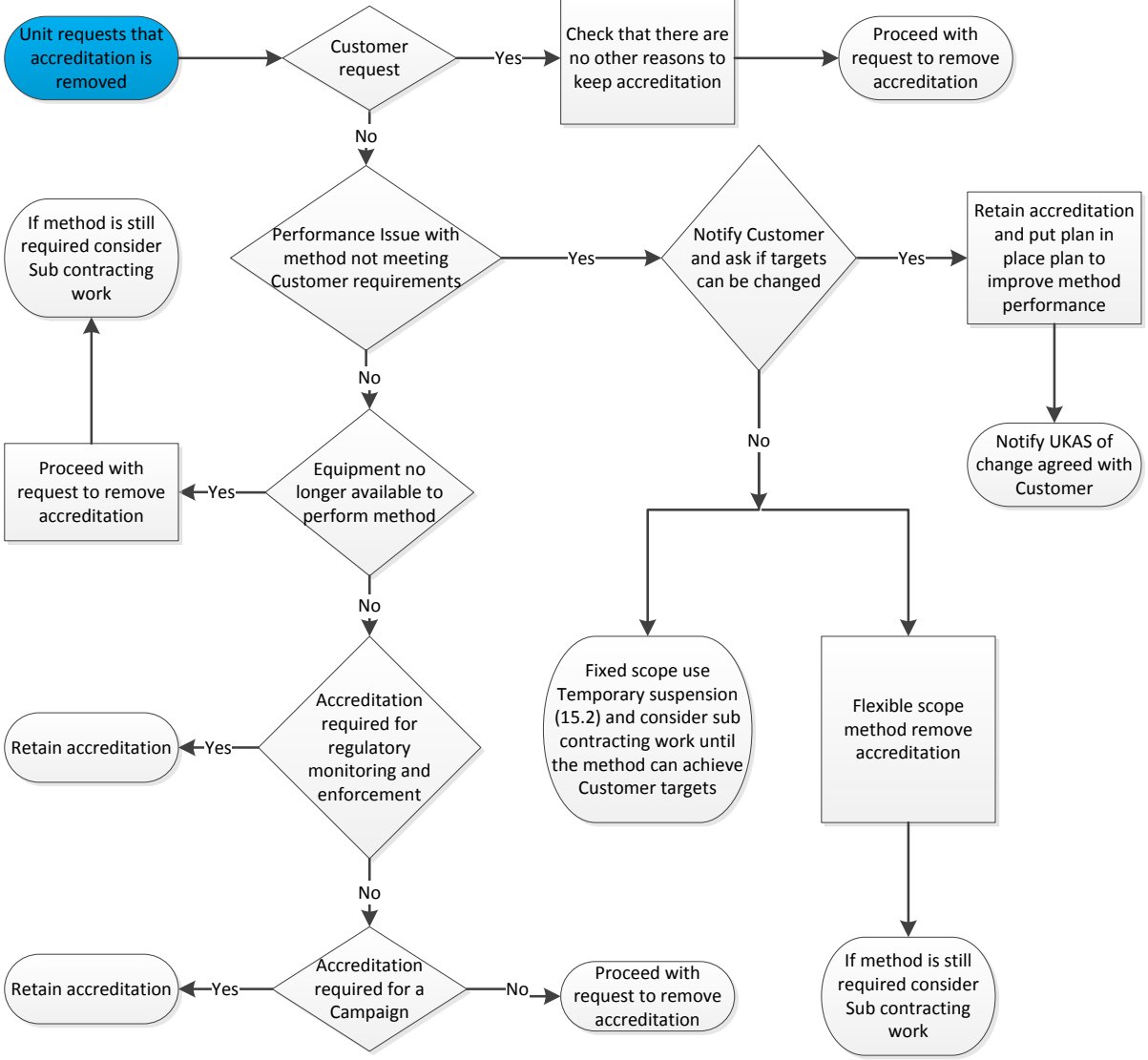
13 Removing and Suspension of Accreditation

13.1 The process below describes the steps necessary when the Unit is considering removing accreditation for a test from either the Fixed or Flexible Scope.

When a Unit wants to remove a method from the schedule of accredited tests, they need to consider the original reasons for the decision to seek accreditation. If this reason is still valid then it may not be possible to remove the accreditation status. Note for all suspensions or removals of accreditation a completed and approved NEMS change request form must be sent to the NEMS helpdesk for action. The Unit must inform the customer of any changes to accreditation status for a method.

The flow diagram below will guide the decision making process.

Removal of Accreditation



If changes to accreditation are identified as possible using the above flow chart, approval at a higher level must be obtained before they can be implemented.

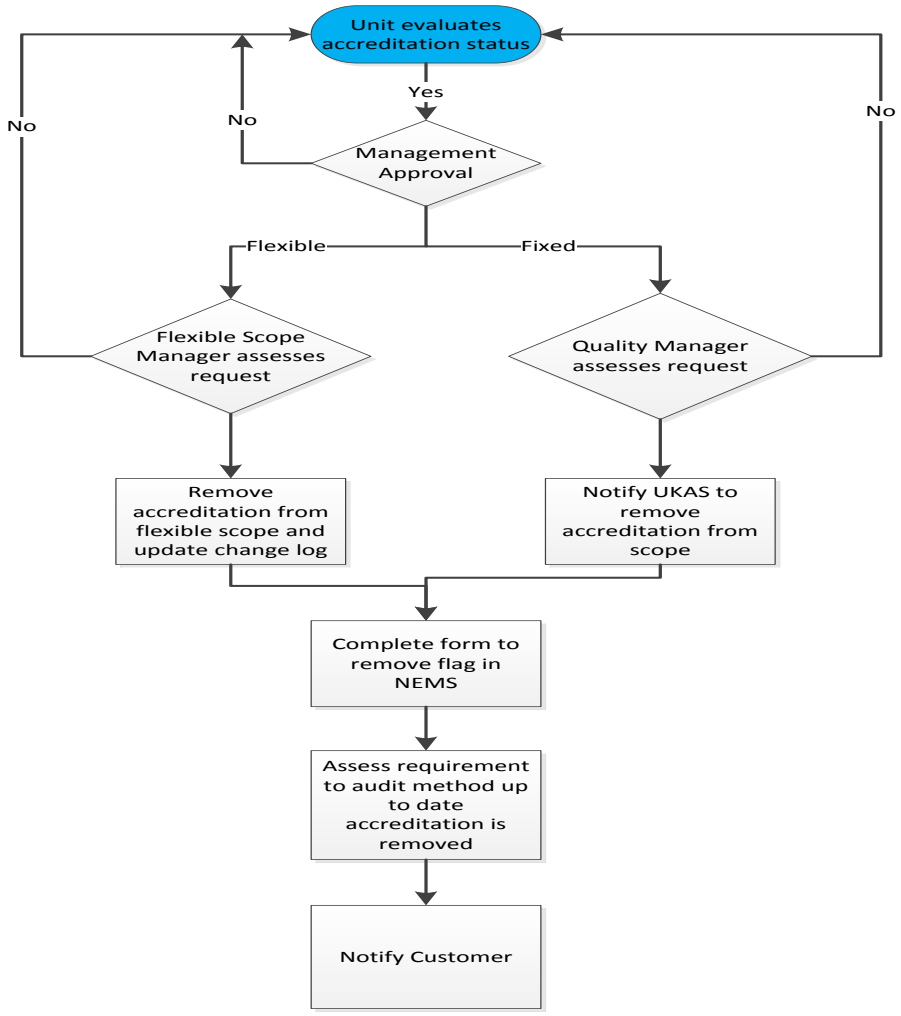
13.2 Approval process for removing accreditation

Fixed Scope methods

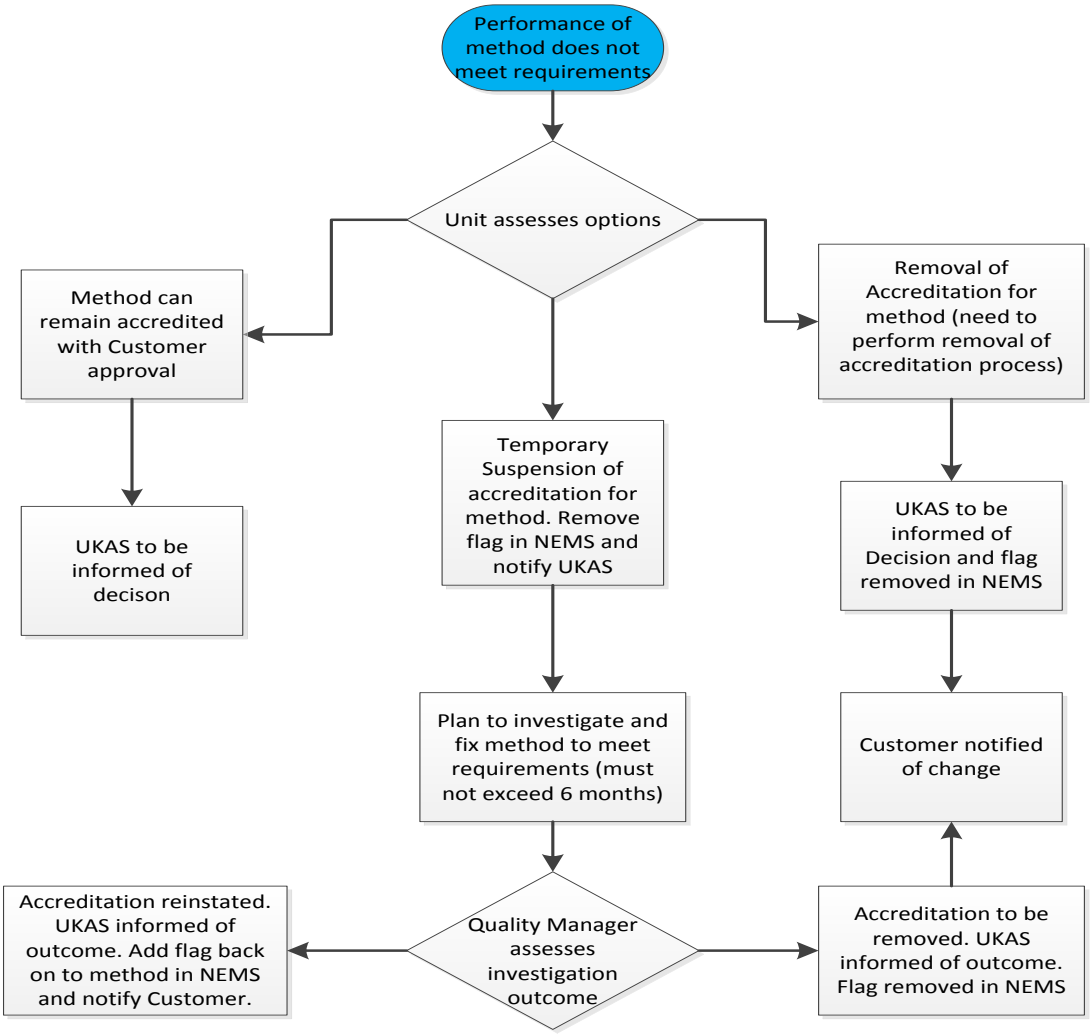
The Unit decides using decision matrix that the method accreditation should be removed. The unit manager approves the change and passes the request to the Manager of the LQS team for approval. Once approved the Senior Business Consultant (with responsibility for ISO 17025) notifies the UKAS assessment manager of the method they wish to withdraw from the scope of accreditation. The Unit then notifies the customer and NEMS team of changes. The method should then be removed from the audit programme (BF 19.11). Finally a check should be made to see when the last audit for this method was performed, and consideration given to a vertical close-out audit.

Flexible Scope methods

The Unit decides (using the decision matrix) that the method accreditation should be removed and notifies the Flexible Scope Manager who removes it from the Flexible Scope and the Unit organises for NEMS flag status to be changed. The Flexible Scope Manager can also approach the Unit to discuss removal of accreditation or an extension to the date if the method is at the end of the time agreed for it to remain accredited.



13.3 Temporary suspension of Accreditation (only applies to Fixed Scope accreditation). A test may be voluntarily suspended from the Fixed Scope of accreditation if SEPA cannot meet performance requirements (e.g. issues with the method, loss of trained personnel, or instrument performance). The Unit should notify the QM who will subsequently inform the UKAS Assessment Manager of the desire for a temporary suspension of a method from our scope of accreditation. There is then a 6 month timeframe from this notification to complete work in-house and demonstrate that the method is fit for purpose. UKAS will contact the QM after 3 months to check on progress. All data to demonstrate the method is now fit for purpose should be submitted by the 6 month deadline. If the method is not fit-for purpose at this stage it must be withdrawn from scope, and any subsequent applications to include it again must be done through the ETS process.



14 Records

All records pertaining to changes in accreditation status should be retained for a minimum of 6 years.

15 References

15.1 BS EN ISO/TEC 17025:2005 – General requirements for the competence of testing and calibration laboratories.

15.2 LAB 39 – UKAS Guidance on the Implementation and Management of Flexible Scopes of Accreditation within Laboratories.

15.3 EA-2/15 M:2008 EA Requirements for the Accreditation of Flexible Scopes.

15.4 EA-2/05 - The scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing.

15.5 ISO 17025:2005 Scope for laboratory 1327 on the UKAS website (here)

16 Related Documents

16.1 BF-213 Science Accreditation change record

16.2 SS-FS-TR-001 Validation Lead Competency Record Template

16.3 SS-FS-TR-002 Flexible Scope Technical Assessor Competency Record

16.4 SS-FS-TR-003 Team Validation Lead selection spreadsheet

16.5 SS-FS-TR-004 Flexible Scope Manager Competency Record

16.6 SS-FS-TR-004 Flexible Scope Development Team Validation Lead Competency Record

16.7 BF-019.15 Technical Assessor Review form

16.8 BF-019.17 Technical Assessor Review Form for Standard Methods

16.9 BF-019.18 Technical Assessor Review Form for Sampling

16.10 BF-021 Template for ISO-17025 Flexible Scope Schedule

16.11 BF-022 Customer Acceptance Memo

16.12 BF-023 Accreditation Change Request Log

16.13 BF-019.16 Quality Audit of Flexible Scope Process

16.14 BP-UKAS-01 UKAS Organisation

16.15 OBP-059.01 Waste Sampling - Creating a Sample Plan

16.16 OBF-059.01 Waste Sampling – Sample Plan

16.17 OBF-059.02 Waste Sampling - Sample Record

16.18 OBF-059.03 Waste Sampling – Sample Record Volume Calculator

16.19 ES-MICRO-P-001 Sampling of Waters for Microbiological Analysis

16.20 ES-MICRO-P-002 Sampling Shellfish for Microbiological Analysis

16.21 ES-CHEM-P-100 Chemical Sampling of Waters

16.22 ES-CHEM-P-100-A1 Chemical Sampling of Waters - Bottle Atlas

16.23 ES-CHEM-P-100-A2 Chemical Sampling of Waters - Urban Wastewater Treatment Directive (UWWTD) Sampling Locations & Analysis

16.24 ES-CHEM-P-102 Analytical Target Times for Water Analysis

16.25 ES-NFC-WP-003 Soil Sampling Method

16.26 ES-NFC-WF-003 Soil Sampling Worksheet

16.27 ES-NFC-WP-003A Soil Sampling: Land Management Questionnaire

16.28 ES-VALID-P-009 Method Validation for Chemical Tests

16.29 ES-VALID-P-010 Method Validation for Field Based Chemical Tests

16.30 ES-MICRO-P-011 Microbiological Analytical Method Validation

16.31 BP-001 SEPA Quality Policy and Manual

16.32 BF-019.11 Science UKAS audit plan.

16.33 NEMS-BF-004 NEMS Media table change request form

Appendix 1 Matrix names and definitions

This list is not exclusive and is supplied for guidance.

UKAS gives guidance on standard definitions for water matrices on its website at UKAS Guidance on Water Matrices Definitions for Sampling and Testing to ISO/IEC 17025.

These are listed as:

- Ground Water
- Surface Water
- Drinking Water
- Land Leachate
- Prepared Leachate
- Untreated Sewage
- Treated Sewage
- Trade Effluent
- Saline Water
- Process Water
- Recreational Water

Any new methods should use these matrix names and definitions for water based matrices. Existing accredited methods have a number of types listed for water matrices which will eventually be mapped to the new water definitions (see table below for how these are related to the guidance matrices).

Guidance matrix names	Matrix names used by SEPA on accredited methods			
Ground Water	Groundwater			
Surface Water	Surface Water Water	Freshwaters Stream waters	Low Ionic Strength Waters Standing waters	Poorly Buffered Fresh Waters (Surface, River and Lake Waters)
Drinking Water	Not used on SEPA scope of accreditation			
Land Leachate	Land Leachate	Landfill leachate		
Prepared Leachate	Leachability of particle size <4mm			
Untreated Sewage	Untreated Effluent	Untreated Domestic		
Treated Sewage	Treated Effluent	Final Effluent	Treated Domestic Wastewater	Treated Domestic
Trade Effluent	Trade Effluent	Industrial Waters	Industrial Effluent	
Saline Water	Saline Waters			

Process Water	Not used on SEPA scope of accreditation			
Recreational Water	Not used on SEPA scope of accreditation			

SEPA also analyses a wide variety of other matrix types and for these there is a list of currently used types below (black from UKAS scope, red proposed names for future use):

Solid

- Sediments
- Marine sediments
- Soils
- Contaminated Soil
- Waste
- Mixed
- Specific

Liquids

- Oils
- Solvents
- Liquids (non aqueous)

Biota

- Shellfish
- Herbage (plants)
- Fish

Air

- Ambient air
- Landfill gas
- Stack emissions

Misc.

- Filter papers and rinse solutions

Appendix 2 Technical Assessment of Sampling Plans

Note - SEPA do not have Flexible accreditation for sampling

Sampling will be conducted using one of the following procedures depending on the type of samples to be collected:

Waste sampling

- OBP-059.01 Waste Sampling - Creating a Sample Plan and Collecting a Sample
- OBF-059.01 Waste Sampling – Sample Plan
- OBF-059.02 Waste Sampling - Sample Record
- OBF-059.03 Waste Sampling – Sample Record Volume Calculator

Microbiology Sampling

- ES-MICRO-P-001 Sampling of Waters for Microbiological Analysis
- ES-MICRO-P-002 Sampling of Shellfish for Microbiological Analysis
- ES-MICRO-L-XXXX where XXXX is the individual site document number for Bathing Water Sampling Location Manual. There are 86 specific site plans in Q-Pulse for Bathing Waters with each one having a map, grid reference, written directions, signage information and Safety notes.

Water Sampling

- ES-CHEM-P-100 Chemical Sampling of Waters
- ES-CHEM-P-100-A1 Chemical Sampling of Waters - Bottle Atlas
- ES-CHEM-P-100-A2 Chemical Sampling of Waters - Urban Wastewater Treatment Directive (UWWTD) Sampling Locations & Analysis
- ES-CHEM-P-102 Analytical Target Times for Water Analysis

Soil Sampling

- ES-NFC-WP-003 Soil Sampling – Method
- ES-NFC-WF-003 Soil Sampling – Worksheet
- ES-NFC-WP-003A Soil Sampling – Land Management Questionnaire

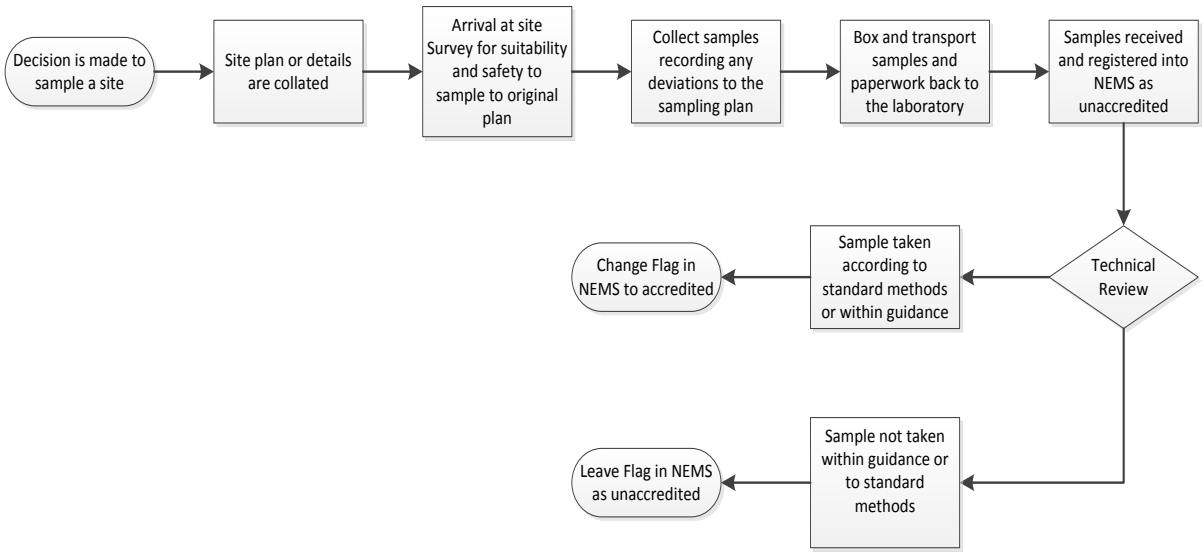
General sampling protocol

- OBP-057.01 Site Sampling and Testing

Sampling generally adheres to the following pattern:

1. Selection of site / site sample plan
2. Arrival at site / Site Survey and update of sampling plan if required.
3. Sampling conducted – due to changes on site due to environmental changes etc. the sit sampling plan may again require updating.
4. Samples boxed and packaged for transportation back to laboratory.
5. Samples transported to laboratory.
6. Samples received and registered into NEMS.

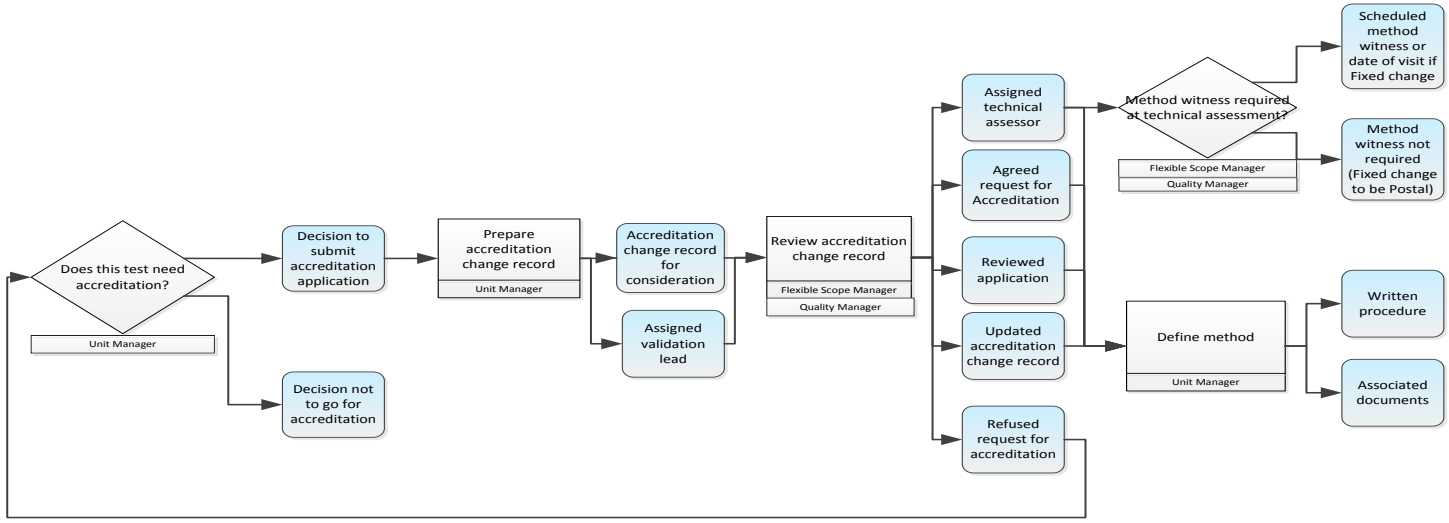
Flow diagram for sample collection and review.



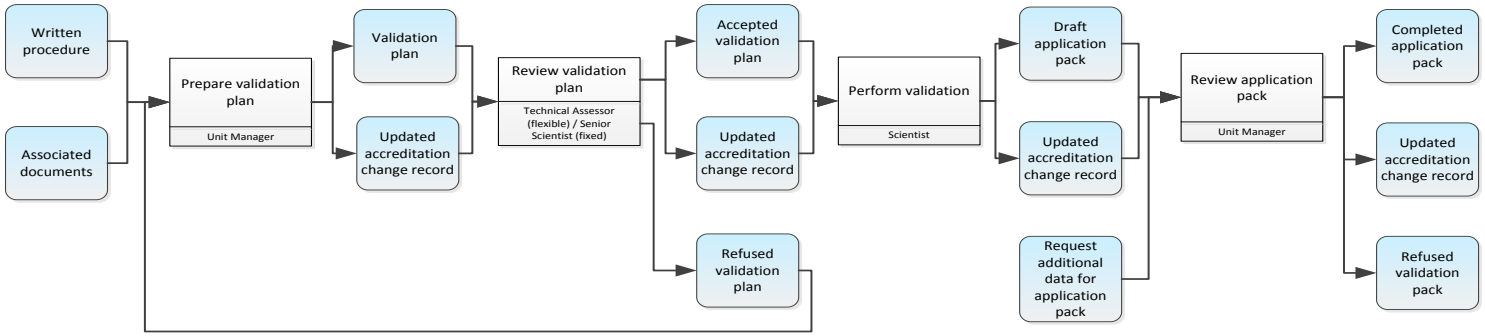
The site sampling plan may change between design and sampling therefore the assessment and review for whether samples can be reported as accredited can only be completed once the samples have been received at the laboratory. This review is conducted by a Technical Assessor using the BF-019.18 Technical Assessor Review Form for Sampling to decide the accreditation status for each sample.

Appendix 3 Process Maps

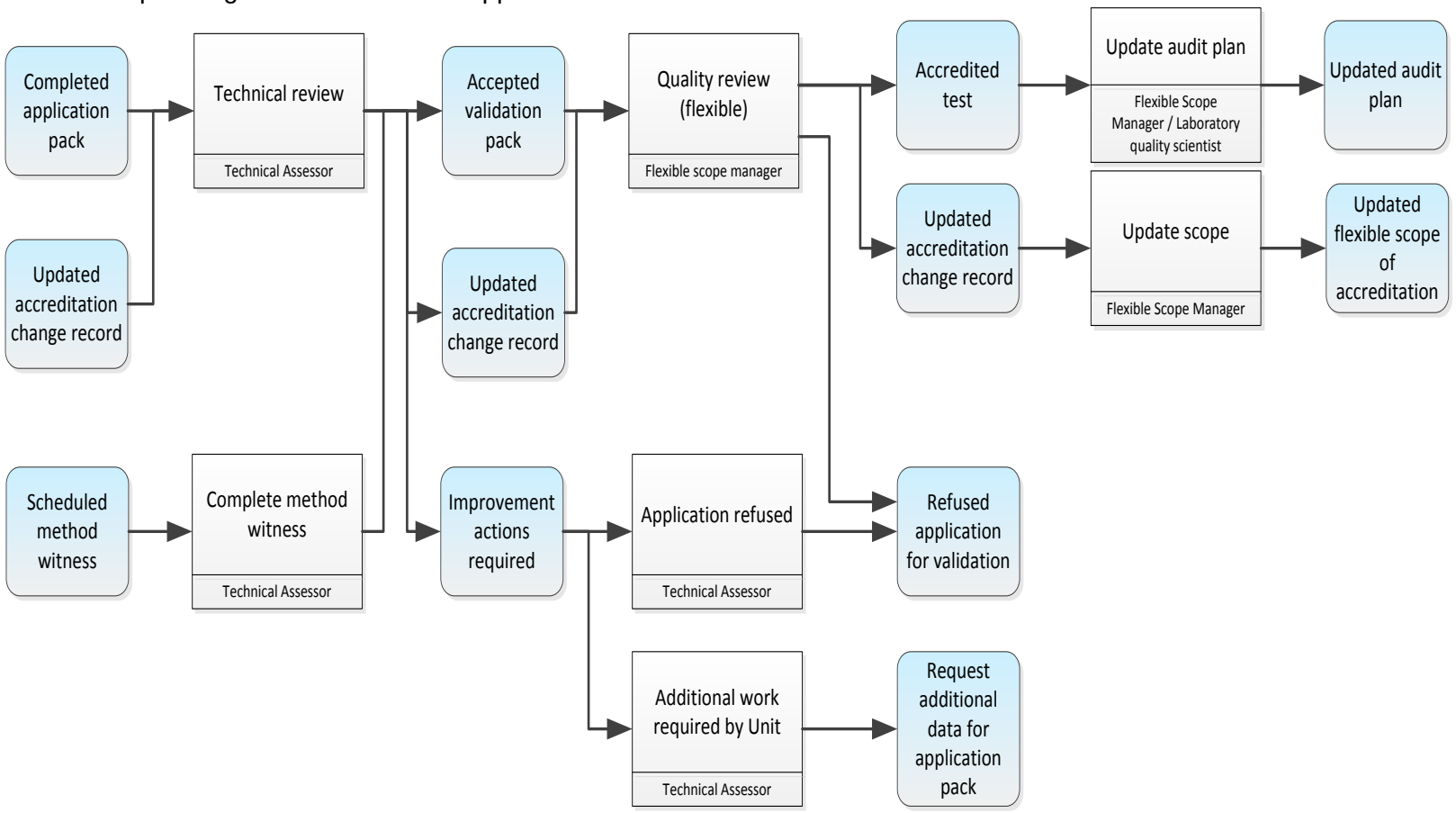
- Process map Stage 1 How SEPA evaluates the requirement for accreditation changes to add methods.



- Process map – Stage 2 Validation of proposed changes fixed or flexible



- Process map – Stage 3 Assessment of Application Flexible



- Process map – Stage 3 Assessment of Application Fixed