



# TPS 59

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## Implementation and Management of Flexible Scopes of Accreditation for the Commissioning of Site Laboratories

*Supplement to UKAS Publication Lab 39*

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## 1 INTRODUCTION

- 1.1 It is recognised that for some fields of testing, laboratories may need to establish site laboratories to serve specific customer requirements. These site laboratories often need to be commissioned at short notice and/or operate for a short period of time. In order for the activities of each site laboratory to be included within the scope of the laboratory's accreditation UKAS is able to grant accreditation for a flexible scope which includes the commissioning of site laboratories.
- 1.2 The purpose of this document is to supplement the guidance given in *LAB 39 - UKAS Guidance on the implementation and Management of Flexible Scopes of Accreditation within Laboratories*, and *TPS 51 - Accreditation of Multi-Site/Group Laboratories* so that a laboratory is able to demonstrate its competence to manage the commissioning of site laboratories within the scope of its ISO/IEC 17025 accreditation.
- 1.3 A laboratory may decide to apply for such a flexible scope where it is necessary to establish and operate a site laboratory at short notice and/or where this activity occurs frequently. A flexible scope in this context will allow a laboratory to include a new site location for all or part of its existing accredited activities within its scope of accreditation prior to an assessment visit (see 4.2).
- 1.4 This approach is optional and alternatively laboratories may decide to apply for an extension to scope for each new location as required.

## 2 APPLICATION FOR ACCREDITATION (see also *Lab 39, Clause 5*)

- 2.1 Where a laboratory identifies a need for this type of flexible scope or wishes to extend its existing scope to include this activity a formal application shall be made to UKAS. This application shall be accompanied by the laboratory's documentation describing how such site facilities are established, resourced, managed and monitored. The laboratory shall also identify the anticipated range of sampling and testing that will be included within this flexible scope.
- 2.2 Prior to offering accreditation for a flexible scope UKAS must have a high degree of confidence that the laboratory staff are competent to manage and operate their processes for establishing site laboratories and that these processes are robust and effective. For existing accredited laboratories that have previously been assessed for extensions to scope for site laboratories, UKAS will have prior knowledge of their competence and ability to maintain their systems. For a new laboratory UKAS will not have this prior knowledge and will have to adopt an assessment approach that will allow confidence to be established; this will require the direct assessment of the commissioning process for new site laboratories.

### **3 ASSESSMENT OF APPLICANT (see also *Lab 39, Clause 6*)**

- 3.1 The assessment of an applicant will examine the laboratory's ability to establish and operate and manage new site laboratories in accordance with their documented procedures and the requirements of ISO/IEC 17025 and will include:
- (a) the application of the laboratory's contract review process to ensure there is a clear definition of the extent of, and any limitations to, the site laboratory's activities;
  - (b) the competence and capability to establish and operate a site laboratory including its processes for commissioning and verifying the performance of equipment and procedures in accordance with the performance characteristics of its existing accredited activities;
  - (c) the training and monitoring of technical staff assigned to the site;
  - (d) the application of the laboratory's management system to all activities that take place at the site laboratory including: quality control and quality assurance measures, measurement traceability, internal auditing and reporting of results;

### **4 ACCREDITATION (see also *Lab 39, Clause 8*)**

- 4.1 The competence of a laboratory to commission site laboratories will be assessed by UKAS and will be recognised by a specific entry on the schedule of accreditation. The extent of the flexibility this provides will be agreed with UKAS and clearly defined on the schedule as well as within the laboratory's operating procedures or processes.
- 4.2 When a new location is established under the flexible scope the laboratory shall provide the following details to UKAS:
- (a) the location of the site laboratory;
  - (b) contact details of the laboratory's representative on site;
  - (c) the sampling and testing activities to be carried out at the location;
  - (d) the date from which the site will operate under accreditation and expected completion date.

UKAS will update the schedule of accreditation accordingly, and will usually make arrangements for an assessment visit to the new location within three months. Assessment visits to site laboratories set up under the flexible scope will normally be planned on the same basis as surveillance visits to permanent laboratories; in other words a selection of the accredited activities will be assessed during each visit, which would be expected to be carried out at annual intervals. However, in circumstances where an organisation is operating several concurrent site laboratories with similar scopes of accreditation, assessment of the organisation may not require the assessment of all operating site locations in each year of operation.

- 4.3 UKAS reserves the right to plan the number, and scope, of visits to site locations accredited under a flexible scope as necessary to maintain confidence in the organisation's operation of that flexible scope.
- 4.4 The laboratory shall inform UKAS of the date when any location will cease to be included in their scope of accreditation. Where closure of a site laboratory is likely to occur before the planned date of the next routine visit, UKAS reserves the right to visit the laboratory prior to the closure in order to ensure that the accreditation requirements have been maintained.
- 4.5 It is recognised that there are organisations operating site laboratories without permanent laboratory facilities and that, on occasion, these organisations may not have any site laboratories operating either. Where this occurs, the laboratory may retain its accredited status as long as it is able to demonstrate continuing competence for its accredited activities. Where an organisation has not operated a site laboratory for more than 12 months, UKAS reserves the right to conduct an assessment at the next available site laboratory prior to the organisation including that location within its scope of accredited work.
- 4.6 Accreditation for the operation of site laboratories under a flexible scope places a greater responsibility with an accredited organisation for making and justifying decisions relating to the inclusion of a particular site laboratory within the scope of accreditation. Where a laboratory fails to maintain its management system, and/or effectively implement its procedures and controls, appropriate sanctions will be imposed by UKAS. Such sanctions may include:
- (a) revocation of the laboratory's ability to operate a flexible scope of accreditation;
  - (b) suspension of accreditation for a specific location or locations;
  - (c) A combination of other sanctions ranging from amendment of the flexible scope to the total suspension of all accredited activities.

## 5 DEFINING THE SCOPE OF ACCREDITATION

- 5.1 The scope of accreditation for all organisations operating site laboratories will be detailed on the multi-site schedule format.
- 5.2 Accreditation for a flexible scope will be recognised by a statement on the schedule of accreditation together with any other information needed to define the scope accurately.
- 5.3 All locations notified to UKAS will be listed on the schedule, and included with the location codes against the relevant accredited activities in the detailed part of the schedule.
- 5.4 The flexible scope will include only activities (sampling and testing) included in the original application. Any increase in the range of activities to be included in the flexible scope will be subject to the usual extension to scope procedures.

### Contact

For further information about this statement, contact your Assessment Manager or UKAS Information (tel 0208 917 8400 email [info@ukas.com](mailto:info@ukas.com))