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General Principles for the Assessment of Inspection Bodies by the United Kingdom Accreditation Service

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CHANGES SINCE LAST EDITION

The document has undergone minor revision and update to reflect current practice and the revised reporting process as described in UKAS Publication GEN 3. Further guidance is also given for the assessment of multi-locations and key activities.

1 INTRODUCTION

- 1.1 One of the functions of UKAS is to assess and accredit the competence of inspection bodies to carry out specified fields and types of inspection and subsequently to ensure by monitoring that the required standards are maintained. Each applicant inspection body provides basic information to UKAS on its activities, equipment and staff in the Application form, (available from the UKAS website www.ukas.com) and its quality documentation. Assessment of the competence of an inspection body is carried out using document review, visits to the inspection body's central administrative office and other locations and on-site assessment of inspections. The purpose of the assessment is to determine whether an inspection body complies with the requirements of ISO/IEC 17020:1998, and applicable Requirements and Guidance (RG) documents. European guidelines on the application of ISO/IEC 17020 are provided in EA/IAF/ILAC-A4: 2004 (see UKAS website www.ukas.com for Publications).
- 1.2 UKAS uses technical assessors with the relevant specialist knowledge to assess the competence of the inspection body to perform the inspections for which accreditation is sought. The assessors are required by UKAS to maintain confidentiality, and to sign a Code of Conduct specifying the need to declare any potential for conflict of interest. Their activities will be confined to assessing the inspection body's activities for compliance with the requirements and reporting their findings to the inspection body and to UKAS.
- 1.3 All information obtained before, during or after assessment, including the fact that a particular inspection body has applied for accreditation, or that an application has been deferred or rejected, will be treated as strictly confidential by UKAS staff and assessors.
- 1.4 This document outlines how UKAS plans and conducts assessment, surveillance and reassessment visits to inspection bodies working to ISO/IEC 17020 on a four year cycle. It also refers to the assessment techniques normally used.

2 DEFINITIONS

- 2.1 **Site** Place at which inspection is being undertaken.
- 2.2 **Multi-location organisation** An organisation with a central office in which key activities are performed or managed with a network of locations at which such activities are fully or partially carried out. All locations have a direct legal or contractual link with the central office of the organisation and are subject to a common quality system.

3 APPLICATION

3.1 (a) On receipt of an application for accreditation as an inspection body working to ISO/IEC 17020, UKAS will appoint an assessment manager to be responsible for the accreditation process. The assessment manager will contact the inspection body to:

(i) seek agreement to the appointment of a specified external Lead Assessor, as appropriate;

(ii) confirm the detailed list of fields and type of inspection for which the organisation is seeking accreditation;

(iii) confirm the different locations from which the inspection service is managed and the whether key activities are carried out at each of these.

Note: For Inspection Bodies key activities include: policy formulation, development of processes and procedures, selection of inspectors, contract review, planning inspections, review and any approval of inspections

When considering whether a premise is one where key activities are carried out, the issues which have an influence on the outcome of inspection should be considered.

Issues for consideration as to whether a premise is one where key activities are carried out may include:

- *Contract review separate from head office;*
- *Maintenance of records not kept at head office;*
- *Maintenance of management system documentation not kept at head office;*
- *Maintenance and calibration of specific equipment kept separate from head office*

(b) Whenever it is necessary for UKAS to make use of external assessors or experts in the assessment of an inspection body, the agreement of the inspection body to the individuals concerned will always be sought.

3.2 Prior to any work being carried out, UKAS will provide an estimate of the effort (in man-days) which will be required to proceed to the next stage of the assessment process. The charges for the UKAS assessment activity are calculated by multiplying this effort by the daily rate in force at the time.

3.3 The inspection body's quality manual and procedures will be examined for compliance with ISO/IEC 17020, EA/IAF/ILAC-A4: 2004, the UKAS Agreement and relevant Requirements and Guidance (RG) documents. If necessary the findings will be reported to the inspection body in order that any changes can be made.

4 PRE-ASSESSMENT

- 4.1 (a) Although not mandatory, a pre-assessment visit would normally be carried out at a specified location (generally the central office) of the inspection body to:
- (i) discuss any findings related to the review of documentation;
 - (ii) seek further information on quality system;
 - (iii) briefly examine the systems which have been established and implemented;
 - (iv) discuss any arrangements which have been made to include multiple locations, inspectors working from home or overseas, subcontracted activities within the quality system;
 - (v) agree the proposed scope of accreditation;
 - (vi) determine whether any further technical assessors will be required.
- (b) The pre-assessment visit will normally be completed within one day.
- 4.2 The Lead Assessor will report his/her findings to UKAS. The report will highlight the main outcomes of the pre-assessment visit and will give an indication on the next step e.g. whether plans for initial assessment can proceed. A copy of the report of the pre-assessment visit will be provided to the IB either at the visit or shortly after.
- 4.3 The inspection body may need to make changes to its policies, procedures and practices prior to UKAS undertaking the assessment.
- 4.4 If necessary, further technical assessors or technical experts will be identified and the agreement of the inspection body to their appointment will be sought.

5 ASSESSMENT

- 5.1 (a) Prior to assessment, the inspection body may be requested to provide UKAS with a list of current inspectors, the fields and types of activity and the locations (however named) at which they are currently operating. This information will enable the Assessment Manager to plan the assessment and take into account all the factors necessary to enable a reliable assessment of the inspection body's competence to carry out the inspections included in the scope of application. The planning process will determine, in conjunction with the inspection body, the sampling level of locations and which inspectors will be subject to on-site assessment (see 5.5).
- (b) An assessment plan and a quotation will be forwarded to the inspection body in advance of the assessment.
- (c) The time required for assessment, surveillance and reassessment will be dependent on the complexity of the organisation, the geographical spread of its activities, the structure of the quality system and the proposed scope of accreditation.

- (d) Following successful assessment, an estimate of the time required to maintain accreditation over the four year cycle, including the anticipated number of locations to be visited and on-site assessments of inspections, will be provided when accreditation is offered; this will be reviewed annually and in the light of any findings. Extensions to scope will be quoted separately.
- (e) The nature of the initial assessment will be dependent upon the scope of accreditation required by the inspection body and the complexity of the quality system that is being operated. However, the following elements will need to be covered:
 - (i) central office assessment
 - (ii) assessment of all locations where key activities take place
 - (iii) on-site assessments of inspections for different fields and types of inspection and inspectors.
- (f) The team for initial assessments will normally comprise a minimum of two persons, one of whom will normally be a permanent UKAS staff member
- (g) When assessing very small inspection bodies UKAS will take into consideration the simplicity of the operational activities of such very small businesses and will apply its assessment process accordingly.

5.2 Central office assessment

5.2.1 The UKAS assessment team will seek to establish through objective evidence and by using various techniques that:

- (a) the inspection body is competent to perform the inspections
- (b) the quality system is appropriated to the inspection body's needs, organisations arrangements and methods of operation, including multiple location operations and number of inspectors;
- (c) all of the requirements of ISO/IEC 17020 have been satisfactorily addressed;
- (d) the inspection body has implemented all the requirements of the quality system effectively;
- (e) the operational, administrative and technical procedures used to support the quality system and inspection activities are complete, technically valid and appropriate.

5.2.2 The following techniques and activities will be employed to establish that procedures are being correctly and fully implemented:

- (a) questioning of management and staff who have an involvement in or bearing upon the quality of inspection work;
- (b) examination of records;
- (c) examination of the suitability, maintenance, calibration, control and use of all facilities and equipment used for inspection work;
- (d) examination of the arrangement for exercising control over subcontractors and suppliers.

- 5.2.3 All fields and types of inspection will be subject to an office assessment and technical review. The team will assess the technical competence of inspectors in each main field or type of inspection covered by the schedule. This will be done through:
- (a) the examination of the records outlined above;
 - (b) discussions with supervisors;
 - (c) assessment of the performance of the staff whilst conducting scheduled inspections (see 5.5).
- 5.2.4 The process for reporting UKAS Assessments is described in UKAS Publication GEN 3 *Reporting UKAS Assessments*. A report will be provided to the inspection body at the time of assessment; where improvement action by the inspection body is required, a maximum of 3 months will normally be allowed for provision of evidence that the action has been carried out. In most cases evidence can be provided by post although there may be situations where additional visits to the inspection body will be required. UKAS will review the evidence provided and decide upon its acceptability.
- 5.2.5 Where the recommendation to accredit (in full or for a reduced scope) has been agreed by UKAS, the decision will be confirmed in writing with the Proposed Accreditation Details. A copy of the draft schedule will also be provided to the Inspection Body. The Inspection Body shall agree these details.
- 5.2.6 Once the assessment team is satisfied that all findings have been satisfactorily actioned, accreditation is granted. The grant letter is sent to the Inspection Body with an Accreditation Certificate and a schedule detailing the agreed inspection activities.
- 5.2.7 Where the assessment team is unable to recommend accreditation for the full scope of the application, UKAS will confirm the decision in writing within one month of the assessment visit.
- 5.2.8 If the Inspection Body disagrees with the accreditation decision taken by UKAS, it may appeal. The appeal must be in writing and must be received by UKAS within one month of the decision letter. The UKAS Appeals Process is published on the UKAS website, www.ukas.com.

5.3 Multi-location organisations

- 5.3.1 (a) On application, the inspection body must indicate the number and range of locations being operated. At initial assessment, UKAS will visit all locations where key activities take place.
- (b) It will normally not be necessary to witness the full range of scopes for each selected location.
- 5.3.2 (a) In addition to 5.2 above, UKAS will seek to establish through objective evidence and by using various techniques that:
- (i) all locations are operating under the same quality system;
 - (ii) all locations are included in the internal audit programme and central review process.
- (b) Temporary locations or locations where 'non key' activities take place must be working to the same requirements and may be subject to assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system.

- (c) During the assessment of any 'key' location, UKAS may need to see records of certain activities which are being carried out at different locations.
- 5.3.3
- (a) If UKAS observes nonconformities at the central office or at any one of the locations of an organisation with multiple locations, the improvement action procedure shall apply to all locations where applicable. In the event that the results of any of the assessments of sample locations reveal that there is a significant weakness or inconsistency in the application of the quality system, UKAS will review the assessment programme and may increase the number of locations to be assessed.
 - (b) Failure by one location to comply with UKAS requirements may lead to removal of the location from the schedule of accreditation. If the cause of nonconformity is the lack of central control then the corporate accreditation will be the subject of review by UKAS and may lead to suspension or withdrawal of accreditation from all locations.
- 5.3.4 Generally, each key activity location from which an organisation is operating will be visited at least once during the four year assessment cycle in addition to the annual visit to the central office.
- 5.3.5 UKAS must be advised of any changes to location addresses and activities. The establishment of any new locations from which the inspection body proposes to offer an accredited service must be notified to UKAS before these can be included in the scope of accreditation; the need for assessment of the new location will be reviewed, the schedule of accreditation will be amended as appropriate and the location will be included in the programme of surveillance and reassessment.

5.5 On-site assessment of inspections

- 5.5.1 On-site assessment of inspections is an essential part of the UKAS assessment of inspection bodies to ISO/IEC 17020. This is particularly important when the inspection body is performing inspections of such a nature where the inspector's professional judgement is crucial to the outcome of inspection.
- 5.5.2 (a) When deciding on the number of on-site assessments of inspections needed the following aspects, at least, will be considered by UKAS:
- (i) the fields and types of inspection on the accreditation schedule;
 - (ii) the inspection body's procedures for selecting, training authorising and monitoring inspectors, having regard to the qualifications and experience required for different fields and types of inspection;
 - (iii) the internal auditing arrangements of the inspection body;
 - (iv) the locations from which inspectors operate;
 - (v) any statutory requirements;
 - (vi) the extent to which inspectors are required to exercise professional judgement;
 - (vii) the number of inspectors;
 - (viii) frequency of inspections;
 - (ix) competence requirements of inspectors e.g. personnel certification or formal qualification.

- (b) The minimum number of on-site assessments of inspections at initial assessment will normally be two.
 - (c) As a minimum, one inspector carrying out inspections will be assessed on-site for the fields and types of inspection on the accreditation schedule.
- 5.5.3 (a) When deciding on which inspectors will be assessed account will be taken of:
- (i) new recruits or new authorisations;
 - (ii) qualifications and experience;
 - (iii) location;
 - (iv) any statutory requirements;
 - (v) the extent to which inspectors are required to exercise professional judgement.
- (b) If none of the inspectors can cover the entire scope of a specific field then more than one inspector will be assessed for that field. Where there is any evidence which casts doubt on the competence of inspection staff, the sample size of inspectors assessed on site may be increased.
- 5.5.4 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an inspector operates from home, this examination will be arranged at a mutually acceptable location.
- 5.5.5 (a) UKAS assessors will ensure that their role during on-site assessment of inspections is one of observer and they will not influence the inspection being performed.
- (b) The team will be looking to see that as a minimum:
- (i) the inspector has the competence for the inspection performed;
 - (ii) the inspector's competence is consistent with the competence criteria;
 - (iii) the inspector has been supplied with all necessary documented inspection methods, procedures and equipment;
 - (iv) the procedures are up-to-date;
 - (v) the inspector implements the procedure in full and correctly ie no short-cuts, no personalised application where it is not permissible to do so;
 - (vi) records of all observations are made while on site as required by the procedure;
 - (vii) records clearly identify what has been inspected, using what method/procedure and when;
 - (viii) all records are authorised and controlled as applicable;
 - (ix) all findings that indicate immediate or urgent action are reported as required to the client whilst on site;

(x) reports comply with the inspection body requirements and ISO/IEC 17020 as amplified by EA/IAF/ILAC-A4: 2004, relevant RG documents and any relevant statutory requirements;

(xi) facilities and equipment are fit for the inspection purpose.

6 SURVEILLANCE AND REASSESSMENT

6.1 General

6.1.1 Following accreditation, UKAS will check for continuing compliance with UKAS requirements by carrying out surveillance visits to inspection bodies, initially six months after accreditation and then annually, with a reassessment in the fourth year. The level of sampling of locations and inspectors will depend on performance over the four year cycle, the extent of any changes which have taken place and the level of confidence which can be placed in the performance measures and control systems of the inspection body (see also criteria in 5.5 above). Quotations will be provided prior to any work being undertaken by UKAS.

6.2 Surveillance

6.2.1 Surveillance visits will be planned to cover the whole of the scope of accreditation over a four yearly cycle. Any revisions to the quality system will be reviewed during these visits; extensive changes may require additional assessment time.

6.2.2 A report will be provided to the inspection body at the time of the surveillance; where improvement action by the inspection body is required, a maximum of one month will normally be allowed for provision of evidence that the action has been carried out. In most cases evidence can be provided by post although there may be situations where additional visits to the inspection body will be required. UKAS will review the evidence provided and decide upon its acceptability.

6.3 On-site assessment of inspections

6.3.1 On-site assessment of inspections will be normally be carried out at each surveillance visit. The same criteria used for assessment will be considered when determining the number and type of inspections, and the inspectors to be witnessed.

6.4 Reassessment

6.4.1 Reassessment visits will involve a comprehensive re-examination of the inspection body's quality system and inspection activities and will be similar in format and content to the initial assessment. The same criteria used for assessment will be considered when determining the number and type of inspections, and the inspectors to be assessed.

6.4.2 The requirements for completion of close out of nonconformities and submission of evidence to UKAS are as for surveillance.

7 EXTENSIONS TO SCOPE

- 7.1 (a) Following receipt of an application for extension to scope UKAS will determine whether or not there is a need for a central office and/or location assessment and/or on-site assessments of inspection to take place. Factors which will be taken into consideration will be the:
- (i) existing scope of accreditation;
 - (ii) inspector competences within scopes;
 - (iii) the range of scopes;
 - (iv) the location at which the extension to scope is sought.
- (b) Where possible and desirable, any additional work will be carried out at the next surveillance or reassessment visit; where necessary, additional visits will be arranged. The estimated effort required for subsequent surveillance and reassessment will be reviewed and may be revised.
- (c) When improvement action by the inspection body is required following assessment for extension of scope, a maximum of 3 months will normally be allowed for provision of evidence that the action has been carried out. Following review and acceptance of the evidence provided, the scope of accreditation will be revised accordingly.

8 SCOPE OF ACCREDITATION

- 8.1 (a) It is UKAS policy to define the scope of an inspection body's accreditation as precisely as possible. Inspection bodies will therefore be asked to specify in detail the field, type and range of inspections for which accreditation is sought and the locations at which these activities are to be carried out, this scope will be agreed as far as possible before the assessment in order to determine the extent of the assessment activities. Following successful assessment, the scope, including standard specifications, methods and procedures relevant to the inspections concerned will be identified on the accreditation schedule.
- (b) Following accreditation, the schedule is considered to be in the public domain unless otherwise requested by the inspection body for legitimate reasons and will be published on www.ukas.com, Inspection Body Schedules.