



C2

EDITION 2 | March 2006

General Principles for the Assessment of Certification Bodies for Product Certification

CONTENTS

	SECTION	PAGE
1	Introduction	2
2	References	2
3	Definitions (from ISO/IEC Guide 2:1996 and ISO/IEC Guide 65)	2
4	Types of Product Certification Schemes	3
5	Product Scheme Requirements	4
6	Assessment Process	5
7	UKAS Assessment Teams	9
8	Appendix 1 - Contract review for individual product certification schemes	11
9	Appendix 2 - The role of the product specialists	12

CHANGES SINCE LAST EDITION

The document has undergone revision to clarify UKAS practice for selecting activities and premises for assessment and more closely to define time limits for clearance of non-conformances. UKAS is currently reviewing the process for reporting assessment findings so the contents of this document will be subject to further change.

1 INTRODUCTION

- 1.1 One of the functions of UKAS is to assess and accredit the competence of certification bodies to carry out product certification and subsequently to ensure by monitoring that the required standards are maintained.
- 1.2 Each applicant certification body provides information to UKAS on its activities, organisation and staff.
- 1.3 Assessment of the competence of a certification body is carried out using document review of the product scheme criteria, and associated standards where applicable, assessment of the certification body's head office management controls, (and other locations if applicable), assessment of testing arrangements (where applicable), and witnessed audits.
- 1.4 The purpose of the assessment is to determine whether a certification body complies with the requirements of EN 45011/(ISO/IEC Guide 65) and applicable guidance documents.
- 1.5 All information obtained before, during or after assessment, including the fact that a particular certification 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, and specialist technical advisors.
- 1.6 This document outlines how UKAS plans and conducts assessments, surveillance and reassessment visits to Certification Bodies working to EN 45011 (Guide 65) on a four-year cycle. It also refers to the assessment techniques normally used.
 - 1.6.1 Every organisation is unique and the assessment plan must recognise this. However, a structure is needed within which judgements are made. By outlining the minimum requirements this document provides such a structure.
 - 1.6.2 All circumstances cannot be anticipated and it may necessary to deviate from these requirements, in order to conduct an effective assessment. UKAS will provide the reason for the use of any alternative approach.

2 References

EN 45011 (ISO/IEC Guide 65) ; General requirements for bodies operating product certification systems.

EA –6/01;EA Guidelines on the application of EN 45011.

ISO/IEC DIS Guide 67 (Draft); Fundamentals of product certification.

3 Definitions (from ISO/IEC Guide 2:1996 and ISO/IEC Guide 65)

3.1 Product certification:

Procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements. 'Product' is used here to include product, process or service.

3.2 Product certification system:

A system that has its own rules of procedure and management for carrying out product certification.

3.3 Product certification scheme:

Product certification system as related to specified products to which the same particular standards and rules, and the same procedure, apply.

3.4 Certification of conformity:

Action by a third party, demonstrating that adequate confidence is provided that a duly identified product is in conformity with a specific standard or other normative document.

3.5 Licence (for certification):

Documents issued under the rules of a certification system, by which a certification body grants to a person or body, the rights to use certificates or marks of conformity for its products in accordance with the rules of the relevant certification scheme.

3.6 Mark of Conformity:

Protected mark, applied or issued under the rules of a certification system, indicating that adequate confidence is provided that the relevant product is in conformity with a specific standard or normative document.

4 Types of Product Certification Schemes

Elements of product certification systems, of which one or more may be included in a given product certification scheme, and upon which product evaluation and certification decisions are made, are:

- ◆ type testing or examination
- ◆ testing or inspection of samples taken from the market or from the supplier's stock, or both
- ◆ testing or inspection of every product or of a particular product, whether new or already in use
- ◆ batch testing or inspection
- ◆ design appraisal

These may be supported by:

- ◆ audit and surveillance of supplier's quality system
- ◆ arrangements for licensing the supplier to use certificates or marks
- ◆ arrangements for on-going audit of the products

UKAS accredited product certification schemes in the majority of cases fall into two categories and ultimately into one, these are:

4.1 Product Type Approval:

Where a sample of the product type is evaluated. ie, a supplier submits a sample "typical" of the product to be manufactured and the certification body confirms compliance with the standard or normative document, a type approval certificate is issued by the certification body. As there is no audit of the supplier's capability to control manufacture, test/inspect the product, storage, or quality management systems etc, or any ongoing product checks, then the supplier cannot apply any mark to the product which indicates the marked product complies with the standard. The supplier can only confirm that a product of the type (purchased say) has been

tested (at some time previous) and found to be compliant with the standard. The certification body does not have any ongoing involvement with the supplier or the product once a type approval certificate has been issued, and in fact it is the supplier's responsibility to resubmit the product for re examination if/when the supplier feels any modifications to the product design or construction significantly changes the validity of the type approval certificate.

- 4.2 "Full" Product certification involves the same type approval checks (evaluation of the design of the product, inspection, test against the criteria of the standard/normative document), followed by an audit of the suppliers manufacturing controls, quality controls and quality management systems as applicable to the product.

(Note, many product schemes require a full ISO 9001 quality management systems (qms) to be in place and assessed, others require qms as applicable to manufacture/quality control - generally known as "fpc" factory production control).

The supplier is awarded certification for the product and is allowed to mark every product with the certification body mark, confirming that the specific product (supplied) does in fact comply with the standard/normative document. The confidence that the certification body has to allow use of their mark in this way is established via the satisfactory audit of the supplier and ONGOING SURVEILLANCE VISITS TO THE SUPPLIER along with independent selection and testing/inspection of AUDIT SAMPLES.

The audit sample is taken and inspected/tested to:

- 1) Confirm the actual sample taken continues to meet the standard/normative document requirements, and
- 2) Confirm the supplier's inspection and test records of acceptable product, and in conjunction with surveillance of qms/fpc and manufacturing controls, that continuing confidence in the product conformance is assured.

5 Product Scheme Requirements

Product certification schemes must be based on technically suitable normative documents which define the specification for product conformance and which have been formulated in conjunction with representatives from the relevant industry sector. The scheme must be designed to be:

- ◆ capable of delivering conforming products consistently (**specification**);
- ◆ capable of being consistently applied by producers to deliver conforming products (**applicability**).
- ◆ capable of being certified consistently (**certifiable**)

The scheme requirements are normally described in a certification body's scheme document (a product specific manual, or a protocol or similar) and references to any applicable National/International Standards are quoted, similarly legislation requirements would also be identified. The scheme document will also contain any additional requirements that the supplier has to satisfy, eg, qms criteria, (which may be by reference to an ISO 9001 certified quality system, or only those requirements for manufacturing/quality control and testing as applicable). In addition the product sampling requirements for initial type testing and for audit sampling should be specified. The scheme document should contain all the information a supplier would need to know in order to obtain certification of the product.

6 Assessment Process

UKAS will assess how product certification bodies are organised to address all the elements that are appropriate to the particular schemes for products on their accreditation schedules in accordance with EN45011/Guide 65. Particular attention will be paid to:

- ◆ the certification body's overall product certification system in terms of input from interested parties to ensure impartiality, and its ability to ensure competent certification to EN45011/Guide 65;
- ◆ the structure and adequacy of each product certification scheme in question in terms of technical suitability for the production of products, and input from interested parties to ensure meeting market expectations technically;
- ◆ the competences of certification body personnel and their understanding of the products and schemes in question;
- ◆ the relationship of voluntary certification of products to any statutory/regulatory requirements for conformity of the product.

6.1 INITIAL ASSESSMENT PROCESS FOR APPLICATIONS

- ◆ contract review
- ◆ planning
- ◆ document review
- ◆ pre-assessment visit
- ◆ head office assessment
- ◆ assessment of critical local or regional offices
- ◆ witnessed audits
- ◆ verification of corrective actions
- ◆ reporting
- ◆ accreditation decision
- ◆ forward planning

6.1.1 Contract Review (see Appendix 1)

A contract review will be carried out for each application to consider the competences necessary for UKAS to assess effectively each product certification scheme applied for.

In particular, the contract review will:

- ◆ determine if technical support is required in conducting the contract review
- ◆ seek advice on where to obtain such support where necessary
- ◆ clarify the scope of the scheme, the 'elements' involved and the technical standards which apply
- ◆ determine if accreditation has already been granted to any other body for certifying schemes involving the products in the application and, if so, how this has been handled
- ◆ identify the competences required for each area of assessment
- ◆ identify the product specialists who fulfil the competence requirements
- ◆ identify any training requirements needed.

6.1.2 Planning

Planning for assessments will make due provision for the technical assessment of all certification schemes covered by the scope of application, using product specialist expertise as necessary for the technical assessment activities, document review, office assessment, witnessed audits and follow-up close out visits as appropriate.

The visit plan will give details of all intended assessment activities, and identify:

- which product schemes will be technically assessed (at initial assessment this will be all schemes applied for);
- which product areas will require a witnessed audits (although the exact details may not be confirmed until the head office assessment visit);
- which assessors will be involved in which activities.

Note: The visit plan may be completed/amended following the pre assessment visit (see 6.1.4)

6.1.3 Initial document review

In addition to assessing legal documents, quality manual and procedures for compliance with EN45011/Guide 65, the document review will include a technical assessment of the product certification scheme documents, including scheme requirements, standards, auditor competences, guidance documents, audit documents (eg, check lists, reports etc) and content of certificates. The product specialists identified in the contract review will conduct technical assessments of scheme documents.

Any comments or concerns will be formally recorded and fed back to the applicant for additional information, clarification etc.

6.1.4 Pre-assessment visit/meeting

The purpose of pre-assessment is to clarify issues arising from the application and/or document review, and to ensure that UKAS has a full understanding of the organisation of the certification body, the facilities for delivering the product certification schemes (eg, regional offices, interfaces with other parties etc), the structure of the schemes and their “ownership”. It also ensures that both parties have a full understanding of the accreditation process appropriate to the product scheme(s) in question.

6.1.5 Head office assessment

The technical review aspect includes assessment of:

- the technical inputs to the design/development of the scheme
- the input from, and acceptance by, stakeholders in the scheme
- the process for validation of the scheme and the monitoring of on-going acceptability
- availability of technical documents, and their maintenance up to date
- contract reviews/preparations for evaluation carried out by the certification body
- the technical management processes and competence criteria of personnel involved in all stages of audit and certification.
- the arrangements to ensure the integrity of test or inspection work
- personnel competency needs analysis
- the records of personnel training, qualifications and experience
- the product certification decision-making process

The UKAS assessment team must have sufficient product knowledge/expertise to be able to evaluate this effectively, both by document and file scrutiny and by interviewing certification body personnel.

The assessment will also cover the certification body's arrangements for the provision of accredited product certification in accordance with EN45011/Guide 65 criteria. All requirements of the standard will be assessed to confirm that product certification is conducted impartially by technically competent personnel in accordance with the certification body procedures, that the products are evaluated against the standards covered by scope applied for, against all the certification criteria specified in the relevant scheme documents, and that decisions to award certification are clearly made on the basis of the evaluation.

The technical review will be carried out for all schemes applied for at initial assessment.

At subsequent assessments, checks will be made as to whether there have been any changes to the schemes previously assessed, to relevant personnel, industry requirements and relevant legislation. In depth technical reviews will be repeated for a selected number of schemes on the schedule, with appropriate input from product specialists.

6.1.6 Assessment of local/regional offices

Where product certification processes take place at additional locations, assessment visits may also take place at these local or regional offices. At assessment UKAS will visit all locations where activities are conducted or controlled that determine or demonstrate the effectiveness of the certification body's performance of the accredited certification. Assessment will include evaluation of any variations to the product schemes occasioned by particular local regulations/requirements/constraints and the validation of any testing or inspection work performed locally. This will be especially important in countries where there is no mutual recognition agreement covering the accreditation of testing of the products involved, or where the chosen testing facility is not accredited for that work. The key feature is to ascertain that the technical inputs to the certification process do not compromise confidence in the certification of the products.

6.1.7 Witnessed audits

These are to confirm a comprehensive, rigorous audit by the certification body's audit team which is able to demonstrate a thorough understanding of the product certification criteria, product/process knowledge, and the necessary audit skills to assess and determine the effectiveness of the manufacturer's arrangements for control of manufacture and test, and to make the necessary judgement regarding product conformance consistent with the overall scheme requirements.

Witnessed audits may include:

- the inspection of product/processes - if not accredited to EN 45004,
- the evaluation of management systems, factory process control etc.
- the approval process and/or the management of external testing if testing arrangements are not accredited to ISO/IEC 17025.

They will be carried out by a UKAS team with sufficient technical expertise to evaluate the certification body auditor's technical competences in carrying out on-site inspection/audit of all aspects of the product and scheme requirements. The certification body will be required to secure UKAS access to their clients for the purpose of witnessing work.

At initial assessment, sufficient witnessed audits will be arranged to give confidence in the certification body's competence to certify the conformance of the entire scope of products applied for. The minimum number of witnessed audits at initial assessment will normally be two. To ensure that a representative sample of the activities of the certification body is witnessed, UKAS aims to cover approximately one quarter of the scopes applied for through witnessed audits. The number of witnessed audits carried out at subsequent visits will depend

on the size and complexity of the certification body's scope of accredited product schemes, and may be extended if concerns are raised at assessments or in connection with a complaint, about the certification body's performance or competences.

Where the "certified product" is an as-installed system, eg, electrical installation, fire detection system, etc the witnessed audit also includes a site visit where the purpose of the certification body audit is to confirm satisfactory installation and testing of the completed system by competent persons.

6.1.8 Verification of corrective actions

Where findings are raised which involve technical issues, the proposed corrective actions will be referred back, as necessary, to the product specialist(s) to confirm acceptability. Where corrective action by the certification body is required, normally a maximum of 3 months will be allowed for provision of evidence that the action has been carried out. It may be possible for the evidence to be provided by post although there will be situations where additional visits to the certification body are required to verify the effectiveness of the corrective actions. UKAS will review the evidence provided and decide upon its acceptability.

6.1.9 Reporting

The report on the assessment will detail the outcome with respect to each product certification scheme covered, and the confidence in the conformity of the products covered by those schemes. Recommendations for accreditation will not be given where this confidence cannot be clearly demonstrated.

6.1.10 Accreditation decision

This will take into account the use of appropriate technical product specialists in all aspects of the assessment process.

6.2 SURVEILLANCE AND REASSESSMENT

Once product certification schemes have been successfully evaluated at initial assessment, on-going surveillance activities will need to verify that they remain valid. Checks will be made: to see if technical standards or other normative scheme documents have changed and, if so, why, and how such changes have been accommodated by the certification body to review the structure and activities of the certification body's industry advisory arrangements; to review any changes to personnel and the on-going maintenance of their competences.

Surveillance will be carried out through office visits and witnessed audits as appropriate, with the involvement of product specialists where necessary, at the stages similar to the initial assessment.

Reassessment visits will involve a comprehensive re-examination of the certification body's management system and certification activities and will be similar in approach and content to the initial assessment although the emphasis may be different dependent upon performance and changes over the past four year cycle.

The level of sampling of witnessed audits will depend on performance over the four-year cycle, the extent of any changes that have taken place, and the level of confidence that can be placed in the performance measures and control systems of the certification body. Quotations will be provided prior to any work being undertaken by UKAS.

For multi-location organisations, each location will normally be visited at the same frequency as for a single site certification body.

Where corrective action by the certification body is required, a programme for the corrective action must be agreed with UKAS within one month of the visit. The certification body must complete the corrective actions and provide evidence to UKAS normally within one month of the programme being

agreed, but within a maximum of three months in order for accreditation to be maintained. When UKAS does not require evidence of clearance to be submitted the verification of the effectiveness of the actions taken will normally be carried out at the next visit to the certification body, but UKAS reserves the right to carry out this verification at any time after the agreed completion date.

6.3 FORWARD PLANNING

Forward planning for the 4-year surveillance/re-assessment cycle will ensure that the technical reviews of all schemes on the certification body's schedule are repeated at least once during the cycle and more frequently for safety-critical schemes, using appropriate product specialist expertise. Certification bodies with a generic scope of products (ie, containing several schemes of similar products) must be examined at head office annually and at least one witnessed audit selected from the scope.

The certification body assessment file will provide a matrix or similar record to show the extent of UKAS activity for a particular scheme, ie, office assessment, witness assessment (either or both) over the four year cycle. For certification bodies with a consistent proven history of performance, eg, a dedicated product scheme(s) for a particular sector, supported by a "stakeholder committee" drawn from the sector, a stable competent assessor base, proven technical management, and proven consistent assessments, the scope of the annual surveillance visit will reflect this proven status.

Where it is found that a particular product scheme has not been used by the certification body during the four-year cycle, the technical review will determine whether the certification body still retains the necessary competence to certify products to the scheme.

7 UKAS Assessment Teams

UKAS assessment teams will be selected such that, between them, the members have an appropriate knowledge and understanding of the particular industry sector involved, of the product and its associated certification scheme, and of any statutory or regulatory requirements placed on the products in question. They will have sufficient understanding of, and expertise in, the technical aspects of the scheme to be able to evaluate effectively the competence of the certification body's personnel in ensuring the conformity of the products to specification and the suppliers compliance with the scheme.

7.1 Specialist Technical advice

Where a product certification scheme is being assessed for the first time, UKAS will seek advice from appropriate organisations, having due regard to requiring and maintaining confidentiality, on the competences that are needed by UKAS to assess the scheme effectively and on any other matters which need to be addressed by UKAS in its rigorous evaluation of all aspects of the scheme, thereby giving confidence in the accreditation of the scheme and the resulting certification.

Such specialist technical advice will assist the evaluation of the design of a product certification scheme by:

- ◆ advising on **specification**, especially product standards other normative documents, staff competence, the constitution of the industry advisory inputs and any specific regulatory concerns;
- ◆ advising on **applicability**, especially with regard to potential problems likely to be faced by the producers in working to specified scheme criteria;
- ◆ advising on the **certifiability** of schemes in terms of how well prescribed scheme criteria need to be to ensure consistency of assessment.

For details of the role of the product specialists during the assessment process see Appendix 2.

7.2 UKAS Register of Product Specialists

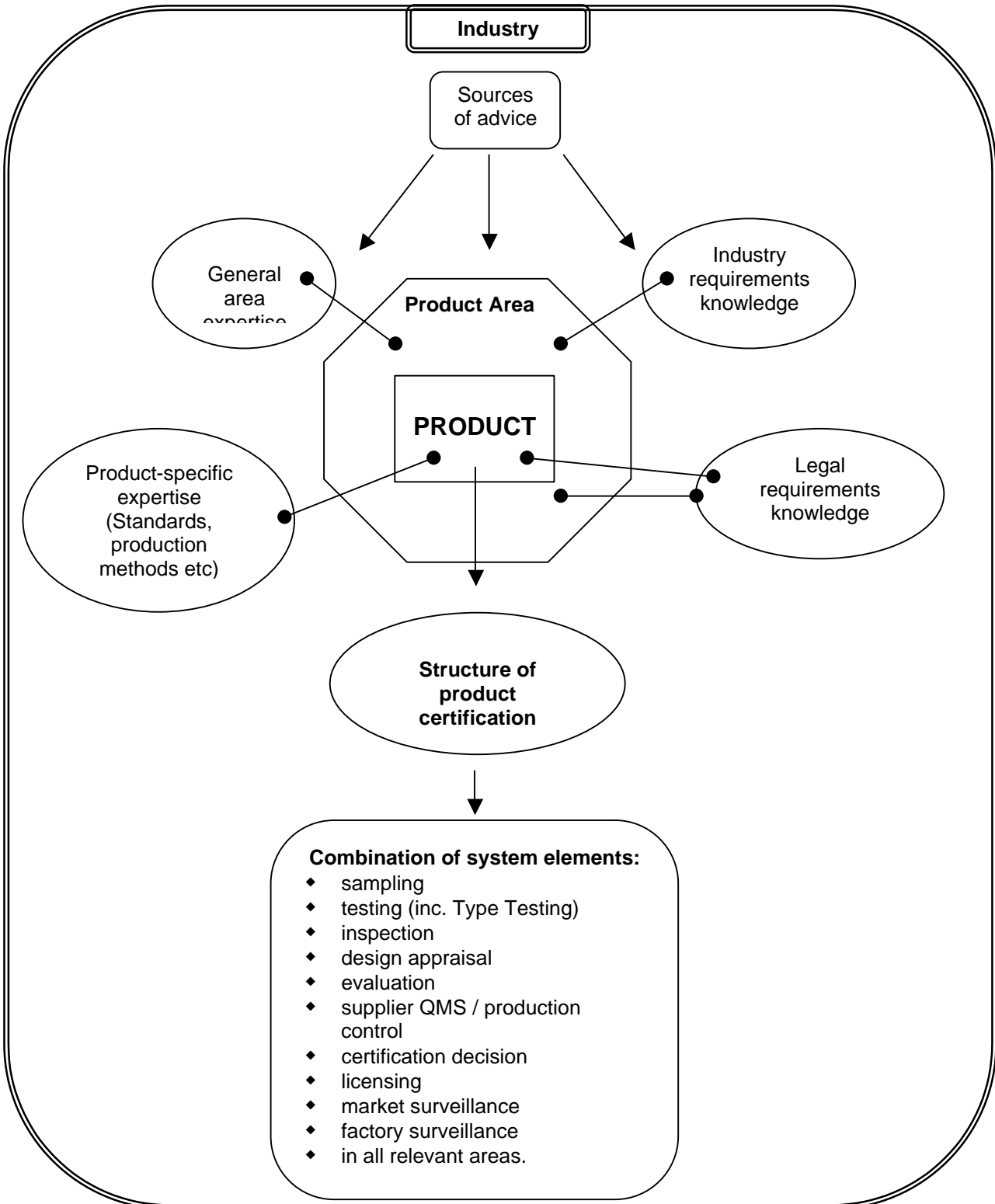
Existing product certification schemes offered by UKAS accredited certification bodies have been categorised under generic families of products (which may be one unique product; or several products of a similar nature etc) for the purpose of identifying product specialists.

A product specialist competence criteria is available for each of the generic products, and any UKAS assessment team must collectively satisfy the product specialist competence criteria in addition to EN 45011/Guide 65 assessment competence.

A new application for a product scheme may be within an existing generic product, the Assessment Manager will refer to the listing during the contract review stage as an aid to determining the product specialism needed. Where the application is for certification of a new product, or an existing product with some unique additions, the specialist competence criteria determined at contract review and the subsequent specialist identified, will be added to the UKAS register.

Appendix 1 - Contract review for individual product certification schemes

The contract review process must take into account the competences needed for all shown below



Appendix 2 - The role of the product specialists

A2.1 REVIEW OF SCHEME DOCUMENT

The UKAS assessment commences with a review of the scheme document. The product specialist, using their knowledge of the product, its manufacture and use etc, and what the declared certification says about the product, will seek to establish the following:

- ◆ *Has the scheme identified ALL the correct standards/criteria for establishing product conformance consistent with the claimed certification?*
- ◆ *If only part of a standard has been referenced, can the claimed certification of the product be justified (without exclusions, or clarification in the wording of the scope of certification)*
- ◆ *Does the initial product sample requirement for “type approval” provide enough of the product for all tests to be carried out?*
- ◆ *If tests specified for audit samples are not the full suite of tests as specified for initial type approval, is the confidence in ongoing product certification justified.*
- ◆ *Does the document specify the sampling regime for audit samples?*

Note1:

Surveillance undertaken by the certification body should give assurance that certified products CONTINUE TO COMPLY WITH the criteria of the standard.

Since audit sampling (and routine checks at the suppliers) by the certification body is intended to provide the independent ongoing confidence and confirmation of product compliance, it is important to confirm the range of products which may be covered by certification, and therefore the range of the products which may require sampling for initial type approval purposes and the range of audit samples for ongoing confirmation. This will be influenced by the differences in the raw materials making up the different ranges/sizes of the same products, differences in manufacturing processes for different ranges/sizes of the same product, additional, or alternative tests for different ranges/sizes of the same product.

If only one product from a wide size range were taken once per year, it could be several years between “surveillance” of the particular product size and confirmation that the product in question continues to comply. The range of products, complexity of the product, raw materials, and the manufacturing processes involved will all influence the audit sample criteria. THE CERTIFICATION BODY must be able to demonstrate that in arriving at the sample size requirements they have considered all relevant parameters associated with the size range of products covered by the certification, and not just specified “once per year a representative sample from production will be taken”.

It may be that for the same products manufactured by two different suppliers, the sampling requirements may be different, depending on such factors as the raw materials, and equipment and processes used to manufacture the full range.

The certification body representative should undertake the physical selection of audit samples for independent testing. Where the certification body allows the client to provide the sample (albeit the certification body nominates the sample type), this arrangement must be by exception and the certification body able to demonstrate, for example, that audit samples and routine samples cannot be tampered with, or that the supplier cannot produce “special samples” for test purposes, and the audit sample must be of recent production.

Note 2:

The certification body may not necessarily own the scheme document; for the purpose of certification the owner may assign it to the certification body. If the scheme document does not specify the inspection/test or surveillance frequency, the certification body will determine the requirements, and if

there is more than one certification body offering the same product certification scheme, these requirements may be different.

The product specialist must evaluate each on its own merit ensuring that the same confidence can be established in the extent and rigour of the assessment arrangements in supporting and demonstrating confidence in the certification of the product.

A2.2 HEAD OFFICE ASSESSMENT

A2.2.1 Scheme Integrity

The role of the product specialist is to ensure that the integrity of the product certification scheme is sound, and that it is capable of delivering what it claims, ie, confidence that each particular certified product does in fact meet the claims made.

It is necessary therefore to;

- ◆ Clarify any aspects of the criteria in the scheme document regarding testing/inspection etc and sampling (as indicated above)
- ◆ Clarify how the certification body developed the scheme, how the stakeholder input was established/obtained, and what arrangements are in place for initiating changes to the scheme and ensuring stakeholder awareness/acceptance of such changes. A certification body must be able to show that the scheme is generally acceptable to the “industry/market” and that any changes affecting the confidence in the product or the claim has been similarly “discussed with interested parties”.

It is important that the certification body is not operating in isolation and has not developed a scheme without input/endorsement/buy-in by the interested parties, and does not/cannot change it at their own whim or the whim of a particular dominant group. (e.g. manufacturers as they feel the cost of testing the full range of samples is too much.)

A certification body must have the technical competence to manage the product scheme including development and validation of the scheme and a mechanism for input from and acceptance by the stakeholders.

A2.2.2 Certification Body Competence Criteria

Product specialists are required to confirm to the UKAS Team Leader that the certification body has defined the competence criteria for the different personnel involved, eg, scheme manager, product specialist and assessor/evaluator, and that the criteria is appropriate and they have records to support the competence of personnel doing the work.

A2.2.3 Testing/Inspection Arrangements

Product specialists are required to examine the testing/inspection arrangements specified and to establish:

- ◆ *If accredited testing/inspection is available for the specified tests?*
- ◆ *If yes, how do the certification body personnel responsible for arranging this know which organisation is accredited, and does their current accredited status contain these tests?*

If accredited testing (inspection) is not available, the certification body must demonstrate what arrangements they have in place to ensure that the test results they obtain provide the same level of confidence as if they were provided by an accredited organisation. (These results are imported into the factors on which the certification body makes the decision to certify the product).

A2.2.4 Review of Product Audit Records

The product specialist review of audit records will seek to confirm the following;

- ◆ *Is it clear what products are certified, e.g., type, size, range. etc?*
- ◆ *Has the type approval process been conducted and all the inspection and tests carried out? Were sufficient samples requested to complete all tests and to justify approval across the range of products certified?*
- ◆ *Were accredited test/inspection facilities used - check labs and their accredited scope.*
- ◆ *If not accredited what did the certification body do, on a case-by-case basis, to ensure integrity/confidence in the output results?*
- ◆ *If a QMS audit is part of the initial product certification audit has it been completed and reported?*
- ◆ *Are there any product related NCRs which may be still outstanding?*
- ◆ *If the certification body accepted the existence of an existing accredited certification of QMS, did the product certification body check the currency/validity of the QMS certificate?*
- ◆ *Does the QMS certificate confirm the scope covers the products in question?*
- ◆ *Was the product certification body satisfied that there were no NCRs currently reported and not closed out which impinge on the confidence in the suppliers ability to produce the product consistently to the specification?*
- ◆ *Did the product certification body confirm the last scheduled surveillance visit had been completed for QMS and that that there were no issues raised which might cast doubt on the supplier's ability to consistently produce compliant product to specification?*

A2.2.5 Surveillance Records

The product specialist review of surveillance records will seek to confirm the following;

- *Does the sampling regime show that the certification body has considered ALL factors relevant to determining the sample size and specific products to be sampled?*
- *Does the history of surveillance/audit sampling show that the product range is sampled?*
- *Are the results of independent testing of audit samples fed back to the supplier?*
- *What happens when audit sample testing results indicate the product has failed?*
- *What is the supplier required to do whilst additional product testing is carried out?*
- *What does the certification body do regarding their confidence in all products certified and put onto the market?*
- *What is the supplier required to do. (Stop marking product, may have to undertake product recall)?*

Where product has failed testing the product specialist will seek to ascertain how this was managed by the certification body or, if there, are no examples will seek to ascertain what the procedures are when this happens.

A2.2.6 Content of Product Certificate

The product specialist review will seek to confirm an accurate description of the certification.

The formal certification documents, such as letter or certificate and/ or "licence" SHALL permit identification of the following:

- The name and address of the supplier
- The scope of the certification granted, including as appropriate;
- the product certified which may be identified by type or range of products
- the product standards or other normative document to which each product is certified
- the applicable certification system (This means reference to type approval, or type approval, QMS and surveillance/audit sampling)* *
- the effective date of certification.

** It should be possible to identify from the information provided what certification system was applicable.