

ASSESSMENT OF APPLICANTS FOR APPOINTMENT AS NOTIFIED BODIES; MONITORING OF NOTIFIED BODIES; AND SURVEILLANCE/ASSESSMENT OF MANUFACTURERS BY NOTIFIED BODIES: SOME PRINCIPLES

Role of Accreditation and UKAS

1. Accreditation to the relevant EN 45000 standard and for a relevant scope carries an element of presumption of conformity to the minimum criteria of the relevant Directive(s). It is not mandatory.

2. Member States are ultimately responsible for the assessment and notification of Notified Bodies. These guidelines have been agreed between Government Departments as a statement of the principles to be observed in the appointment of Notified Bodies. Departments may seek advice from another body acting on the authority of Government for the purposes of the assessment of applicants for notification. DTI, and increasingly other Government Departments, have chosen to use UKAS for the provision of advice in respect of a potential Notified Body's technical competence and of the monitoring and re-assessment of Notified Bodies. This use of UKAS by Departments is in line with Articles 1 and 2(ii) of the DTI's memorandum of understanding with UKAS, which, on behalf of Government, recognise UKAS as the sole accreditation body in the UK and provides that where testing, inspection or certification is required to demonstrate compliance with Directives, Government will normally specify the use of laboratories, inspection bodies or certification bodies accredited or recommended by UKAS. The principles described here constitute the preferred route to be adopted, and Departments have agreed to follow them as far as possible.

3. DTI, and other Government Departments, with the assistance of UKAS, develops guidelines for the assessment of potential Notified Bodies to be appointed under implementing Regulations for specific Directives which:

- provide the detail underpinning the minimum criteria in the relevant Directive(s) for the appointment of Notified Bodies
- take into account the relevant conformity assessment modules or other specified criteria
- use the Essential Requirements of the relevant Directive(s) as implemented to identify, and be able to recommend, the technical competence requirements to be placed on potential Notified Bodies
- relate conformity assessment to the relevant EN 45000 standard(s)
- refer to the relevant product standards where they exist
- bear in mind that accreditation to EN 45000 is not mandatory, but use EN 45000 as the starting point and make clear that full allowance will be made for any pre-existing accreditation

4. Against this background, in using UKAS to provide advice, DTI expects UKAS to:

- use suitably qualified assessors or assessment teams to undertake the assessment of applicants for notification;

- make clear to applicants when sub-contracted assessors are to be used and give applicants the right to object to specific assessors if there are concerns about potential conflicts of interest;
- provide a view on the status of applicants for appointment against the minimum criteria of the relevant Directive(s);
- provide recommendations on applicants' technical competence in respect of (a) the module(s) or other specified conformity assessment procedures those applicants are seeking to employ and (b) the relevant essential requirements of the product range for which the applicant is seeking appointment;
- not to insist that an applicant should also apply for or hold existing accreditation but nonetheless to use the criteria in the relevant EN 45000 standard(s) as far as practicable in assessing technical competence and impartiality;
- take into account relevant UKAS or EA/IAF MLA signatory accreditation already held or applied for by the applicant and not to duplicate any assessment already undertaken but nonetheless to carry out the additional assessment necessary to be able to report to the Secretary of State;
- not to insist on a level of surveillance of a manufacturer's quality system or a frequency of product testing which goes beyond that set out in the Regulations and/or in the Notified Body's letter of appointment from DTI.

Assessment of Competence to Assess Products Directly to Essential Health and Safety Requirements

5. The compliance of products with relevant harmonised standards, produced by the European standards organisations to support specific Directives, is not mandatory but carries a presumption of conformity to the relevant essential requirements of those Directives. In providing advice to the DTI, UKAS should consider potential Notified Bodies in respect of their technical competence to assess products directly to the relevant Essential Requirements of the relevant Directive(s)/implementing Regulations where this is necessary (because of the absence of relevant harmonised standards) or requested by the applicant. This applies regardless of whether the potential Notified Body has also sought UKAS accreditation

NB: Notified Bodies should provide full details of any defective harmonised standard and, if relevant, an inappropriate application of harmonised standards to DTI. Defective standards are those which do not fulfil the mandate issued to the European standards organisations by the Directive 83/189 Article 5 committee, and/or do not allow the essential requirements of the relevant directive to be met in full.

Monitoring of Notified Bodies

6. Once a Notified Body has been appointed by DTI, DTI will generally request UKAS on its behalf to carry out monitoring of that body in accordance with the terms of its DTI letter of appointment and to advise DTI of the results of monitoring. The frequency of that monitoring will generally be consistent with UKAS accreditation practice, that is surveillance annually and full reassessment every four years, following an initial surveillance after 6 months for new applicants, and will be specified in the Notified Body's letter of appointment from DTI.

Additional monitoring may be carried out at more frequent intervals if justified by the circumstances. Witnessed assessments, in which UKAS shall from time to time accompany the Notified Body during the latter's assessment of a manufacturer, shall be one of the methods employed by UKAS in carrying out surveillance/re-assessment of Notified Bodies.

7. In cases where a Notified Body has also been accredited for a scope included within the scope of the relevant Directive(s) as implemented, suspension, withdrawal or reduction of scope of that accreditation as a result of surveillance or reassessment (or at the request of the Notified Body) may result in withdrawal of that Body's Notified body status if DTI is advised that the minimum criteria of the relevant Directive(s) are no longer met.

Assessment/Surveillance of Manufacturers by Notified Bodies (including product testing)

(a) Initial Assessment: Notified Bodies' Treatment of Pre-existing Quality Assurance Certificates

8. Compliance with the relevant part of ISO 9000 carries a presumption of conformity to the quality system elements of modules D, E and H or other criteria specified in the implementing Regulations. Use of ISO 9000 is not mandatory and Notified Bodies must not insist on it. Where a Notified Body is also an accredited ISO 9000 certification body and has issued a manufacturer with an accredited ISO 9000 certificate with a scope relevant to the Regulations under which that Notified Body has been appointed and to the particular product(s) being made by the manufacturer, that Notified Body should presume that the manufacturer's quality systems complies with the quality system elements of the relevant module or other criteria specified in the Regulations for which the manufacturer has applied to the Notified Body for assessment.

9. Where, prior to lodging an application with a Notified Body, a manufacturer already has a relevant ISO 9000 certificate issued by another certification body with an accredited¹ scope included within the scope of the relevant Regulations and covering the particular product(s) being made by the manufacturer, or by another relevant Notified Body, the Notified Body to whom the application is made should take that certificate into account when assessing the quality management system against the relevant requirements of the Regulations. The Notified Body should avoid unnecessary duplication but should nonetheless satisfy itself that the pre-existing certificate is valid and that the quality management system meets the relevant requirements of the Regulations. In connection with this, the Notified Body should take into account the results of surveillance/reassessment carried out by the accredited certification body (or Notified Body) which had issued the pre-existing ISO 9000 certificate.

10. Other ways in which a manufacturer conforms to the relevant harmonised standard supporting modules D, E and H (eg certificates issued by bodies accredited by another accreditation body recognised by the relevant authorities which is not also a signatory to an MLA with UKAS), even if they may not inspire the same degree of confidence, may also be taken into account by the Notified Body.

11. When monitoring Notified Bodies UKAS should take the above into account and should not insist on more frequent surveillance of the quality system or other intervention by the Notified Body than is necessary or specified.

¹ "Accredited" here means accredited by UKAS or by another signatory to an MLA of which UKAS is also a signatory.

(b) Surveillance and Re-assessment

12. Notified Bodies should not carry out market surveillance. Market surveillance is the responsibility of the relevant enforcement authorities and is the monitoring collectively of products, manufacturers, conformity assessment systems and Notified Bodies after an individual product has been placed on to the market. This applies regardless of whether the individual product is one of a batch of identical products, some of which may already have been placed on to the market at an earlier point. Enforcement authorities may use the services of Notified Bodies (preferably not those involved in the original evaluation of the product in question) in order to verify whether a product is in conformity or not, but the final judgement must rest with the enforcement authority and not the Notified Body.²

13. Notified Bodies will be required to carry out surveillance of a manufacturer's quality assurance system operated in accordance with module D, E or H or other criteria specified in the Regulations. The frequency of that surveillance should generally be consistent with UKAS accredited certification practice, that is surveillance at least annually and full reassessment every three years' unless a specific Directive dictates otherwise. Additional surveillance may be carried out at more frequent intervals if justified by the circumstances. In all cases, such surveillance may involve a reasonable level of product testing or inspection to verify that the quality management system is functioning correctly. Where a Notified Body is also accredited for a scope included within the scope of the relevant Regulations and covering the particular product(s) being made by the manufacturer, UKAS shall not insist on more frequent intervals of surveillance of the manufacturer by the Notified Body than is specified in the relevant Regulations. This only applies in respect of the accredited Body's activity undertaken directly in relation to its role as a Notified Body.

14. Where a manufacturer already has an ISO 9000 certificate issued by an accredited certification body, or by another relevant Notified Body, with a scope included in the scope of the relevant Regulations and covering the particular product(s) being made by the manufacturer, the Notified Body undertaking the surveillance and re-assessment referred to in paragraph 13 above should take into account the results of any surveillance/re-assessment undertaken by the body which issued the pre-existing certificate and should avoid duplication as far as possible.

(c) Product Testing/Inspection

15. Where a module provides that the surveillance of the quality management system may also involve tests or inspection, undertaken during unexpected visits to the manufacturer, to verify that the quality system is functioning correctly, it is recognised that the Notified Body may carry out tests on the product where this is necessary to verify the quality system. Unless the Regulations dictate otherwise such tests should generally be confined to instances where clear evidence demonstrates that there is reasonable doubt about the effectiveness of the quality system to ensure that products made under it conform to the essential requirements of the relevant directive. Unless the Regulations dictate otherwise the frequency of unexpected visits and of related product testing or inspection shall be a matter for Notified Bodies to determine at their discretion, and as appropriate following co-ordination with other Notified Bodies, but should not be unreasonable. These principles apply whether or not the

² The Commission's Guide to the Implementation of New Approach Directives is clear that where an enforcement authority also has a role as a Notified Body there must be lines of responsibility to ensure that the functions of pre-market conformity assessment and market surveillance are separate and independent.

Notified Body is also accredited but in the case of an accredited body apply only to those activities directly related to its role as a Notified Body.

16. The Modules Decision requires that Notified Bodies employing modules Aa or G shall be required by member States to carry out testing to determine a product's conformity to essential requirements before that product is placed onto the market. Testing is also required in cases where (a) Module F is employed, to ensure that individual products conform with the Essential Requirements or with an approved type, and (b) when Module C is used in combination with Module B (but only when Module C has been enhanced by either of the supplementary provisions provided for in the Modules Decision). In cases where the frequency of testing is not specified in the relevant Regulations, the frequency shall be a matter for Notified Bodies to determine at their discretion, and as appropriate following co-ordination with other Notified Bodies, but should not be unreasonable³.

17. Where such testing is required and a Notified Body is also accredited for a scope included within the scope of the relevant Regulations, UKAS shall not impose on that Notified Body a requirement to carry out more frequent testing of the product than is required by the relevant Regulations. This only applies in respect of the accredited Body's activity undertaken directly in relation to its role as a notified Body. Notified Bodies may sub-contract some elements of their conformity assessment activity, including testing, but must ensure that their sub-contractors are competent and must themselves take ultimate responsibility for final decisions on whether to confirm product/type conformity.

Insurance

18. Notified Bodies are required to have professional indemnity and public liability insurance from an independent insurer. Evidence of this should be submitted to UKAS and to the DTI at the point at which a body makes an application to be appointed as a Notified Body. Thereafter, the Notified Body should make available to UKAS evidence of insurance at each annual surveillance undertaken by UKAS.

Exchange of Information

19. A recommendation from UKAS to DTI will include supporting documentation such as a copy of the assessor's visit report, a list of identified deficiencies, and the agreed remedial action. Following a recommendation from UKAS, if DTI decides to appoint it will inform UKAS at the point at which the body concerned has been formally appointed as a Notified Body and will provide UKAS with a copy of the letter of appointment.

20. UKAS will advise DTI of the outcome of annual surveillance, four yearly reassessment and any other necessary monitoring in intervening periods of Notified Bodies in order for DTI to take any necessary decisions about the continuation of a Notified Body's appointment. The information provided by UKAS to DTI will include supporting documentation of the type referred to in paragraph 19 and details of any incidents in which a Notified Body is unable to provide evidence of insurance. Such information will relate only to the Notified Body's activities as a notified body and will not include any other accredited activity which is not relevant to the Notified Body's appointment.

³ In most cases the Regulations allow for random product testing, the frequency of which is not specified. The first possible supplement to modules Aa and C, however, specifically requires testing of each product as does module G. Module F provides for the manufacturer to choose either random testing or testing of each product by a Notified Body, unless the relevant Regulations specifies a different frequency.

21. UKAS will advise DTI if it believes that a Notified Body fails to continue to comply with the terms of its letter of appointment, including with the minimum criteria of the relevant Directive(s). In the case of a Notified Body which has also been accredited for a scope included within the scope of the relevant Regulations, UKAS will advise DTI if that accreditation is suspended, withdrawn or reduced in scope and, following any appropriate appeals procedure, will recommend to DTI whether it consider that constitutes a failure to continue to comply with the minimum criteria of the relevant Directive(s). UKAS will notify DTI when an accreditation which supports notification is re-instated following suspension, withdrawal or reduction in scope.

22. DTI will advise UKAS if, for whatever reason, a notified Body has its notification suspended or withdrawn.

DTI/STRD
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