
**DIUS' response to:-
questions on
EC Regulation 765/08
Accreditation and Market Surveillance**

6 February 2009

Preface

This document publishes, verbatim, questions received from 'ConCAss' [**C**onsultation on **C**onformity **A**ssessment – a long standing informal Government consultation group on matters to do with conformity assessment and accreditation] and others that received or read the DIUS information pack on EC Regulation 765/08 (http://www.dius.gov.uk/policy/standardisation/eu_regulation.html) or other attendees at the DIUS Open Day on this Regulation held on 3 December 2008. By publishing these questions DIUS does not necessarily support or agree with (or vice versa) the facts presented, or with the points or arguments made, in the questions.

UKAS (United Kingdom Accreditation Service) has since 1995 been recognised by Government as the sole national accreditation body for the UK for the accreditation, against internationally agreed standards, of organisations that provide certification, testing, inspection and calibration services.

Accreditation by UKAS demonstrates the competence, impartiality and performance capability of these evaluators.

UKAS is sponsored by DIUS and is a DIUS Delivery Partner.

While DIUS owns the responses to these questions they have been prepared in close co-operation with UKAS.

N.B. To save duplicating answers, questions that are the same or are very similar, have been grouped together and where this is the case there follows a single response that answers all the points raised. All DIUS' responses are shown in a blue coloured italic font.

Table of Contents

| <u>Topic</u> | <u>Page</u> |
|--|--------------------|
| 1. National Accreditation Body | 4 |
| 1.1 Monitoring of UK NAB | 4 |
| 1.2 Appeals process | 5 |
| 1.3 Freedom of Information Act | 6 |
| 1.4 Right of choice | 6 |
| 1.5 Fees/Charges | 6 |
| 2. International | 8 |
| 2.1 Monitoring of EA | 8 |
| 2.2 Cross border accreditation | 8 |
| 2.3 International infrastructure | 11 |
| 3. General | 14 |
| 3.1 Non-accredited conformity assessment | 14 |
| 3.2 Questions of scope | 14 |
| 3.2.1 Accreditation: mandatory or voluntary? | 14 |
| 3.2.2 Accreditation and non-harmonised standards | 14 |
| 3.2.3 How the Regulation applies | 15 |
| 3.3 Notified Bodies | 16 |
| 3.4 Other | 17 |
| 4. Glossary | 19 |

1. NATIONAL ACCREDITATION BODIES (NABs)

1.1 Monitoring of UK NAB

- Q As a CB based only in the UK (but operating globally) we will be compelled to obtain our accreditation services only from UKAS and will no longer be able to seek alternative services from, for example, the Dutch body. With UKAS in this new "restrictive monopoly" / public authority position, without being formally made a NDPB, and given recent concerns about UKAS's (1) fee levels, and (2) quality of service, what assurances can HMG offer that (a) UKAS will be kept under scrutiny by HMG to make sure it is serving the interests of UK businesses, (b) suitable service level arrangements will be imposed on UKAS, and (c) that these arrangements will be completely transparent?
- Q Given the regulations will cover NAB activity as it relates primarily to certification bodies, client feedback, performance and results of monitoring should all be reported separately and publicly and not combined with other reports on NAB activity.
- Q In discharge of its responsibility for regular monitoring of the NAB, does Government intend to establish (a) KPIs for the transparent measurement of the NAB's performance? (b) A sanctions regime in support of its responsibility to take corrective actions, as may be necessary, against the NAB? (c) An independent appeals process to consider appeals from NAB stakeholders?
- Q How does Government intend to monitor the "not for profit" status of the NAB? For example, will strict limits be set for the level of NAB reserves to ensure that surplus revenue is used either to fund NAB development activities and/or to reduce the NAB's fees & charges?
- Q Who will audit UKAS?
- Q Where do we go if we are unhappy with them?
- Q DIUS has increased responsibilities for monitoring. As regards the not-for-profit basis, will DIUS set limits on charges, reserves - and salaries?
- Q. I still have some concerns regarding UKAS having a monopoly position in the UK, particularly with respect to the lack of measurable customer based service standards, the effectiveness of peer evaluation, and the "arms length" approach which will be taken by DIUS. I do not believe that having two accreditation bodies in the UK will lead to the "commercialization of accreditation" as it will provide customers with a choice, raise the commercial awareness of the Accreditation body, and help ensure accreditation service standards do not slip
- A. *It should first be noted – in respect of the above questions received – that the Regulation applies to all CABs and not just CBs.*

DIUS monitoring of the NAB against Article 8 of the Regulation

The Regulation [Article 9.2] obliges Member States to monitor its NAB against a NAB's requirements as stated in Article 8 e.g. independence from CABs, attestation decisions taken by competent persons, procedures to ensure efficient management & appropriate internal controls, etc. DIUS will effect this monitoring largely through ongoing review as is the case now (see below) but will also consider the results of the EA Peer Evaluation and 3rd party independent audits commissioned by DIUS.

DIUS monitoring of NAB business performance

There is no specific requirement in the Regulation to monitor a NAB's 'business' performance although Article 4.9 requires Member States to ensure that their NABs have the appropriate financial and personnel resources. DIUS already monitors UKAS' performance using a wealth of information already available to DIUS. This includes, for example, a variety of formal data: business plan, annual report and accounts, customer satisfaction/complaints data; appeals data. DIUS can also monitor UKAS' performance through its position as a Member of UKAS. In addition DIUS staff have regular review meetings with the Chief Executive and Chairman; DIUS is a member (and regular attendee) of the UKAS Policy Advisory Committee; and has independent meetings with stakeholder representatives.

DIUS has in the past commissioned 3rd party independent audits, focusing on UKAS efficiency (e.g. the reports prepared by the consultancy company Hedra) and these will continue (currently these take place once every 4 years). DIUS believes these activities to be proportionate to the requirement but in extremis would have recourse to the NAO for the purposes of conducting an in-depth audit.

Matters such as fees, charges, reserves and salaries are for the UKAS Board. DIUS' role is not to micro manage UKAS which is, in any case, a private organisation. SLAs are not appropriate in this instance as DIUS is not seeking a service, is not going to contract and is not paying any money to UKAS as a result of appointing UKAS as the UK NAB. The UKAS Board, which includes non-executive Directors, reviews pricing structures annually. DIUS will however continue to monitor, fees, charges, reserves and salaries, etc, as part of its general monitoring activities.

That said DIUS is looking into what additional monitoring of UKAS' performance is either required or considered to be beneficial and viable, and will continue to listen to feedback from ConCASS members.

DIUS will have access to EA peer evaluations including (as it has done in the past) the opportunity to ask EA to look at issues other than normal evaluation content.

Monitoring of the NAB other than by DIUS

Other forms of monitoring already take place. UKAS Members (i.e. the major stakeholders) play a part in the governance of UKAS, attend AGMs, are asked to recognise the company accounts and appoint directors.

Transparency of monitoring arrangements

DIUS is in the process of revising the Memorandum of Understanding with UKAS, primarily to reflect the requirements of the regulation. The revised Memorandum, once agreed, will be published on the UKAS website. The structure of the monitoring arrangements will be made clear but the data thus obtained will be subject to normal commercial sensitivities.

1.2 Appeals Process

Q ... my initial concern is that the UKAS appeals process ultimately rests on the decision of the UKAS Director. Legal process beyond this is acknowledged but the process itself cannot be regarded as independent as currently structured. I feel this is a serious failing given the unique position afforded to UKAS by this legislation.

Q DIUS has increased responsibilities for monitoring and the appeals process - does that process include legal remedies?

A *The Regulation requires Member States to establish procedures for the resolution of appeals, including, where appropriate, legal remedies against accreditation decisions or the absence thereof. To meet ISO/IEC 17011 the AB must ultimately make the accreditation decision. UKAS has an appeals process, that has been approved by DIUS and which UKAS cannot change without DIUS approval. This appeals process is robust and has been approved under previous Peer Evaluations. There is provision in the appeals process to involve 3rd party independent advice (that includes advice from DIUS). As part of the implementation process, DIUS will consider formalising these*

arrangements. In addition, in DIUS's view, as accreditation under the Regulation is a public authority activity UKAS will be subject to judicial review if necessary.

1.3 Freedom of Information Act

Q As a NAB will operate as a public authority will the Freedom of Information Act be amended in the Schedule of the Act to include UKAS?

A *As a private company, UKAS is not currently covered by the Freedom of Information Act (FoI) and is unlikely to be covered in the foreseeable future.*

1.4 Right of choice

Q The right of choice?

Q The right of choice - the move towards a single accreditation body for each country is a concern because it will remove the right of choice on where conformity assessment bodies can go for accreditation. In addition, there is potential for abuse of the new monopolies that national accreditation bodies will hold and a danger that the market could become subject to the whim of local interpretations of international standards.

Q The possible abuse of the National Accreditation Bodies (NABs)' monopoly position, and what steps are taken to prevent this.

A *The legal framework seeks to ensure that accreditation is the highest level of control in the conformity assessment chain and operates non-competitively. Under the Regulation a NAB is appointed to operate accreditation as a non-competitive public authority activity; not as a monopoly. Choice of NABs by CABs would effectively create an open market for accreditation and hence competition, which would be contrary to the intention of the Regulation.*

The Regulation itself prescribes a number of safeguards against the possible abuse of a NAB's privileged position. DIUS will look to the peer evaluation system to ensure consistency of approach and interpretation, as well as to ensure the NAB complies with ISO/IEC 17011. DIUS will be monitoring the NAB – see section 1.1 above and will continue to listen to views of ConCass members as the new regime settles down.

1.4 Fees/Charges

Q Does only having one NAB mean a single pricing structure which is the same for corporate and SMEs?

Q What are the cost implications to test labs?

Fees/Charges

The Regulation recognises that accreditation should be self financing. UKAS is a private organisation and will therefore remain the responsibility of the UKAS Board to determine the pricing structure. However, the existing MoU between DIUS and UKAS requires UKAS "to ensure that its fee charging arrangements are fair and reasonable" and this requirement is expected to continue. DIUS considers the fee structure as part of its general monitoring of UKAS.

The Regulation will not, in itself, lead to any increase in the fees that UKAS charges.

Q. Currently assessors' remuneration is affected dependant on the number of actions an assessor raises due to being paid for close out time. This encourages a negative 'policing' culture rather than a positive pragmatic one. As a result, UK PLCs can be burdened with non-value-adding bureaucratic activity following a UKAS audit which can put a crippling effect on resource in smaller labs, thus affecting business income in the short term.

Q If UKAS uses a contract assessor, what safeguards are there where the assessor's remuneration depends on close-out time (meaning spurious issues could theoretically be raised deliberately to increase fees)?

A. *The degree of close-out is very closely monitored by both Assessment Managers responsible for the assessments and the decision makers involved in accreditation decisions. UKAS would strongly object to any suggestion fees might be deliberately inflated. Customers have the opportunity to discuss with assessment teams the actions that they need to take in order to clear outstanding improvement actions and nonconformities. In recent years, UKAS has made changes to its processes for evaluating the effectiveness of certain, low-risk improvement actions such that these are not checked until the next planned assessment. This demonstrates UKAS' commitment to ensure value for money to its customers. DIUS will continue to monitor UKAS fees.*

2.0 International

2.1 Monitoring of EA [European co-operation for Accreditation]

- Q What arrangements will HMG and the Commission be making to monitor the activities of EA in the context of the Regulation, and to ensure that the levels of scrutiny applied by EA on national ABs across the EU, by national EU member states on their ABs, and by the national ABs themselves on their client certification bodies, laboratories and inspection bodies are (a) equivalent across the EU, and (b) of sufficiently high level to prevent EU-wide accreditation being brought into disrepute?
- Q Technical conformity across borders
- Q Equivalence of accreditation - although in theory the quality of accreditation in each EU country will be equivalent and consistent, in reality there is not necessarily mutual recognition in the marketplace due to clear differences in size and level of experience of organisations. Reassurance is needed that safeguards, such as transparent peer evaluations, are in place to ensure that accreditation is of equal and consistent quality across the EU. Member state governments may accept the principle of equivalence of accreditation but they are not, in the main, clients and the market does not work like this in reality.
- Q Equivalence of accreditation across all EU countries?
- A *The Regulation recognises that EA Peer Evaluation is a vital mechanism to delivering equality of scrutiny and consistency of practice. The Commission and stakeholders (via the EA Advisory Board) are currently involved in the oversight of the system and consider that the EA Peer Evaluation process is robust. Nonetheless, EA is currently working to enhance the system specifically to ensure that it meets the requirements of the Regulation. The Commission and Member States are considering whether stakeholder involvement needs to be strengthened and, if so, how. It is likely that the EA Advisory Board will continue to be the main mechanism for these monitoring activities.*
- It should be noted that the arrangements for monitoring at Commission and Member State level remain the subject of discussion with the Commission. DIUS anticipates however that the Senior Officials Group on Standardisation (SOGS)¹ is likely to be the main forum for this discussion.*

2.2 Cross Border Accreditation

- Q Restriction of global operation - at a time when business has moved towards working across a collaborative global arena, there is a concern that, if interpreted to the letter, this new country-by-country approach will create artificial barriers and could restrict ability to operate internationally. This lack of commercial flexibility would clearly be a backwards step and therefore detrimental to the market.
- Q How will this affect CBs who work globally?
- Q How Certification Bodies who hold multiple accreditations will be impacted?
- Q Can International Certification Bodies hold and use more than the local accreditation in a country?
- Q Whatever the principle, by preventing a UK established body from gaining accreditation directly from another EEA body, there will be stakeholder reaction that will impact on the business of UK CABs within other EEA countries.

¹ an ad hoc expert group drawn from Government officials in Member States whose role is as an informal consultation body and to enable information flow on issues of policy concerning standardisation and conformity assessment - including accreditation, market surveillance and other New Approach issues.

- Q Clarity on multi national businesses with multiple legal entities
- Q When is the clarification of Annex B, cl 7.1 expected? (cross frontier)
- Q Clarify how multi national certification bodies with multiple legal entities will have to comply
- Q If CB is established in country X and wants to deliver accredited products in Country Y where it does not have an office will it need to be accredited by the AB from country Y?
- Q How will CABs be obliged to achieve accreditation with their local NAB?
- Q How does this regulation make accreditation across Europe more consistent when all the Country offices of large CBs are accredited by different bodies?
- Q If the local body does not have the full range activities how is the CAB to deal with this?
- Q The customer perspective - it is clear that customers value the global reach and consistency of assessment our members currently provide and would not welcome separation into autonomous legal entities to satisfy the new regulation. Multi-site clients frequently request the provision of one accredited certificate to cover the whole of their local and international activities - will that still be legal in the EU? That would seem consistent with the spirit of the stated objective of the regulation: "to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union" but clarity is needed.
- Q The issue of multinational businesses with multiple legal entities - a key concern is whether members will be able to continue to provide international clients with their current local accredited certificates or will they only be permitted to hold accreditation in their own country in the EU. Our understanding is that the regulation will mean a Conformity Assessment Body (CAB) will be at liberty to seek accreditation from the National Accreditation Body (NAB) in the country of its principal office. But in order to provide local certification in other EU states, it will need to have a separate legal entity in each, holding single-country accreditation for an autonomous business via each relevant NAB. If that is the case, this new approach is likely to have a radical and potentially detrimental strategic impact on competitive effectiveness and organisational structure because of the potential need to decentralise operations. It would create a huge administrative burden through the sheer resource, time and expense demanded by this requirement. This could be seen as discriminatory towards large international organisations providing high quality services and therefore distort competition, as small national companies acting only in their local market will have cost benefits. There is apparent contradiction in the regulation and clearer guidance is needed as soon as possible because of the tight timescale towards implementation in January 2010. This timescale is also problematic given that existing contracts typically commit CABs to deliver accredited certification services for a three-year cycle - as the regulation may change the type of accreditation members are able to offer, how can that be accommodated in the proposed timescale of just over one year?
- Q. If we currently issue UKAS certificates in member states through our sales offices in the countries can we still continue to do that or do we have to obtain the local accreditation from the NAB in the member state and issue their local accredited certificates?
- Q. As we are accredited by UKAS in the UK and all certification decisions are made in UK but in the future we may operate an overseas office as a critical location to make certification decisions for UKAS certificated clients on our behalf. Do we have to have the local accreditation from the NAB in order to do this?

Q. If we change the principle place of establishment from UK to another European country do we have to have the local NAB accreditation to issue UKAS accredited certificates?

A *Article 7 imposes an obligation on Conformity Assessment Bodies that request accreditation, to seek accreditation from the NAB of the Member State in which it is established.*

The ultimate policy intention of the Regulation is to reduce duplication and remove the need to hold multiple accreditation certificates, thus facilitating mutual recognition and promoting the overall acceptance of accreditation certificates and conformity assessment results across the European Economic Area, irrespective of the issuing EEA country of origin. Therefore, an accreditation certificate gained in the UK will be accepted by all EEA national authorities and vice versa. Moreover, it will remove the possibility of National Accreditation Bodies 'competing' for local CAB/laboratory business.

The certificate will also be recognised by MLA signatories so there should be little need for a CAB to seek additional accreditation. If it wishes however to seek accreditation from non-EU ABs, perhaps for commercial reasons, then it is free to do so.

The UK has proposed a preliminary interpretation, based on 3 scenarios (found in Annex C of the DIUS information pack), of the term 'established' as given in article 7.1 and DIUS will be seeking an interpretation that will not require multinational CABs to seek accreditation in each Member State in which they operate. However, the Commission has yet to publish a definitive interpretation and until such time as it does, the Commission considered that a 'business-as-usual' approach was justified. It is likely that Member States will reach consensus on Article 7 interpretation through the 'senior officials group on standardisation and conformity assessment policy' - SOGS.

Article 7 is clear that where a Conformity Assessment Body is solely established in the UK, it should seek accreditation from the UK's National Accreditation Body (UKAS). Moreover, a Conformity Assessment Body solely established in France will seek accreditation from the French National Accreditation Body (COFRAC)....and so forth. The uncertainty of Article 7 concerns the operations of multinational Conformity Assessment Bodies that operate in more than one member state, whether or not they are legally established entities or branch organisations. This situation is under consideration by the Commission, for example, whether a branch organisation is considered a separate entity and therefore requires individual accreditation.

Where a National Accreditation Body receives an application from a CAB established in another Member State, it should reject and redirect the applicants to the appropriate NAB.

Clearly CABs can seek accreditation from other MS' NABs if their local NAB does not have the expertise needed for the scope of accreditation. Although the mechanism has yet to be finalised, the local NAB should be in a position to advise if they do not cover the full scope of the accreditation being sought. If necessary the local NAB should make recommendations for referral or joint working to ensure only one accreditation certificate is issued.

DIUS will ensure that interested parties are kept informed of any progress on this issue.

Q Non-European accreditation - it is unclear whether a non-EU CB will be able to issue an EU accredited certificate if the CB has no separate legal entity in an EU State (for example Japanese CB certifying British company), and whether an EU CB can issue an EU Client with a non-EU accredited certificate when that CB is also accredited outside EU (for example British CB with American accreditation).

A *The Regulation does not prevent EU NABs from accrediting non-EU CBs, whether or not they have a legal identity in EU, nor does it stop non-EU CBs operating in Europe under EU accreditation. Nor do we believe that the Regulation stops EU based CBs from operating under non-EU accreditations. It does however require CBs based in the EU to request accreditation from the NAB of the Member State in which it is established (see above).*

Q Where a CAB has successfully sought accreditation from another NAB (as provided for by Art 7.1), what happens if circumstances change and subsequently accreditation becomes available from the NAB in the member state where it is established?

A *This scenario has not been discussed but we expect that a reasonable transition period will be agreed for the transfer of accreditation.*

2.3 International infrastructure

Q What this means for EA and IAF? Do they need to exist now?

Q Who are the “stakeholders” referred to in Article 10(2) of Reg (EC) No 765/2008?

Q How does Government interpret the right of NAB stakeholders to participate in the system for supervision of peer evaluation? Will stakeholders have access to the evaluation reports bearing in mind that the NAB will enjoy public authority status?

Q What is the risk that overseas NABs will refuse to accept UKAS accreditation? (Annex A - cl 2.5)

Q Cl 2.10 of Annex A allows an NAB to refuse an AB from outside the EEA. How does this fit with the IAF MLA on cross frontier?

Q Recognition of ABs or even NABs outside of "Fortress Europe"

A *EA's pivotal role, and that of Peer Evaluation, in helping deliver the aims of this Regulation has been recognised in the Regulation itself. There will continue to be a need for IAF and ILAC for MLAs covering countries outside the EEA.*

It is expected that stakeholders will participate in the peer evaluation system through their representative organisations via the EA Advisory Board (representatives for CABS; Industry Services and Trade; National Authorities; Consumers; Commission; European Standard Organisations etc). Details of the EA AB membership are available on the EA website.

Evaluation reports are prepared for the EA MAC (Multilateral Agreement Committee). The Regulation requires that EA reports the outcome of peer evaluations to DIUS (as well as to all other Member States and the Commission). DIUS expects to have access to peer evaluation reports relating to UKAS and will take into account what the evaluation has to say but does not expect to make the reports available to the general public. However the outcomes (results) of peer evaluations will be published - refer to Articles 10.2 and 10.6.

NABs do not refuse or accept another NAB's accreditation; this is a matter for Member States with regards to the regulated sector and for the market in the voluntary sector. Within the EEA, national authorities are obliged to accept the results of accreditation under the Regulation. Under the various MLAs, UKAS promotes that accredited reports and certificates that have been issued by bodies accredited by an MLA signatory can be considered to be equally reliable as if they had been issued by a body accredited by UKAS. However, ABs outside Europe will not be required to meet the requirements of Regulation 765/2008 so national authorities, specifiers and the marketplace are free to decide on the acceptability of attestations issued under their accreditation

Q UKAS had a bullet in their presentation that said they would release accreditations of non-UK CABS back to the accreditation body in the relevant Member State however there was no bullet saying that they would accept in accreditations existing in other Member State accreditation bodies?

Q Will UKAS be receiving-in existing stand-alone accreditations?

A. *We anticipate that UKAS will receive some existing stand alone accreditations. The transition arrangements will be discussed and agreed within EA.*

Q Regarding Article 4.1 where other NABs may be used, is translation an added cost that should be considered? The Regulation would, for example, prevent a Conformity

Assessment Body (CAB) using ANAB services, where both speak English, and force the use of a non-English speaking European alternative.

- A. *Translation costs may be an implication in this scenario but we expect UKAS to offer a comprehensive service.*
- Q Concerns about perceived lack of confidence in the IAF and the standards-making process, considered very damaging.
- A. *It is not the intention of the Regulation to impact on the rest of the world outside Europe. The intention of the Regulation is simply to improve European accreditation. No criticism of IAF, ISO/IEC 17011 or the standards making process is implied.*
- Q Who will accredit the accreditors?
- A. *NABs are not accredited but are subjected to a Peer Evaluation under the control of EA. This is fully in accordance with the requirements of the Regulation.*
- Q What is the mechanism for removing the status of a NAB, and has this ever actually been done?
- A. *Member States will have ultimate responsibility for the appointment, and any removal, of the status of NAB within that Member State. EA will evaluate NABs against the requirements of ISO/IEC 17011, the Regulation, and other European and international accreditation requirements in order to grant signatory status to the EA Multilateral Agreement (MLA) (which in the future will be a requirement of the Regulation). EA has, in recent years, both suspended certain EA ABs from the EA MLA and terminated signatory status where the appropriate requirements were not being met.*
- Q What consultation will there be on the next part of the peer evaluation process?
- A. *Input to the EA work to enhance the peer evaluation process can be provided through the EA Advisory Board*
- Q Where are the promised European Commission guidelines for stakeholders? When revised Blue Guide guidance is published, presumably after 2010, there was concern that it would become effective immediately - with the Regulation already being in force - giving no time to adjust.
- A. *The guidelines are at an early draft stage, and are likely to result in a revision of the Blue Guide. That could be quite some time off but it is unlikely that any guidelines agreed would be introduced without transitional arrangements being made.*
- Q One third of all Notified Bodies are established outside of the EU, so the Regulation has no affect on them.
- A. *Notified Bodies must be established in the EU. In relation to CABs nominated under the MRAs, the European Commission has stated that existing MRAs will continue exactly as they are now. Future MRAs may be written to take into account the requirements of Regulation 765/2008.*
- Q What controls will be in place to ensure a common interpretation of accreditation requirements (eg ISO 17021)?
- A. *The harmonisation of accreditation practices is one of EA's main functions allied to the work undertaken by the international accreditation system. It is worth noting that the quality of standards is of primary importance in ensuring common interpretation. EA also maintains a strong influence within ILAC and IAF to aid consistency at the international level.*

Q Is there a potential conflict of interest between EA's mandate under the Regulation and the rules of membership of ILAC: especially in respect of the provisions on Commission and MS supervision of EA and specific requirements in the areas of independence, competition and cross border policy? Will EA or individual NAB members of EA need to withdraw their membership of the ILAC MLA as a result?

A *We do not consider that there is a conflict. Signatory status of the ILAC MLA is based upon successful peer evaluation against ISO/IEC 17011. This will not change with the introduction of the Regulation. EU NABs will operate to different requirements in some respects, eg independence, competition and cross border policy, but we do not consider that this will affect their status in the ILAC MLA. EA has confirmed that it will still recognize the equal reliability of accredited reports and certificates issued by bodies accredited by ILAC and IAF MRA/MLA signatory ABs.*

Q. How will these laws improve the quality of accreditation across the EU?

A. *The Recitals to the Regulation say that the Regulation is required:-*

- *To overcome the lack of common rules that has resulted in different approaches and systems throughout the Community with the result that the degree of rigour applied to the performance of accreditation has varied between Member States.*
- *To introduce a system of accreditation that functions by reference to binding rules thus helping to strengthen mutual confidence between Member States as regards the competence of CABs and consequently the certificates and test reports issued by them.*
- *To prevent competition between NABs and the commercialisation of their activities (which would be incompatible with their role as the last level of control in the conformity assessment chain).*
- *To ensure that one accreditation certificate is sufficient within the EU; avoiding multiple accreditation which is added cost without added value.*

DIUS supports these objectives.

Q. Will you be addressing how best the requirements of this Regulation fit in with the requirements of certain well-established international arrangements such as the IECEE-CB Scheme (covering electrical equipment) and IECQ Scheme (covering components)? Or indeed the CENELEC Certification Agreement (CCA)? While recognising that the Regulation is based on assessment of a laboratory's capabilities by accreditation bodies, the above schemes are based on a technical assessment by Certification Bodies. Nevertheless, the above schemes, and particularly the CB scheme and IECQ are very important for world trade.

A *There is nothing in the Regulation to prevent these schemes continuing.*

3.0 General

3.1 Non-accredited conformity assessment

Q I have corresponded with UKAS for some time re the activities of consultants who offer combined consulting and accreditation services, and are not registered with UKAS. I work on the "shop floor" where this is concerned and am currently helping a small company which has been a victim of one of these organisations. Major sections of the ISO9000:2000 (2008 now) group of documents have simply been ignored. The company has been audited against a so-called quality manual provided by the same organisation, and against which they have been "accredited".

Q. If UKAS is the only national accreditation body recognised by UK government does that mean that the non-UKAS accredited bodies are operating illegally?

A *The regulation does not make accreditation mandatory and the status of non-accredited CABs currently remains unchanged.*

Q What is being done to prevent agencies which are not on the UKAS approved list from claiming accredited status as assessors in the UK?

A *UKAS will take action against any CAB that incorrectly claims UKAS accreditation.*

In addition "The Business Protection from Misleading Marketing Regulations 2008" (BPRs) prohibit misleading business-to-business advertising. Under this legislation complaints can be made to local Trading Standards Services/Office of Fair Trading who can bring civil or criminal proceedings.

3.2 Questions of scope

3.2.1 Accreditation: mandatory or voluntary?

Q Why can't a company assess and apply accreditation to another company to a quality standard like EN 17020 apart from UKAS if they have the necessary expertise and experience?

A *Accreditation remains voluntary unless required by specific legislation. There is nothing to stop a company (that is not the NAB) assessing against for example 17020 but it will not be "accreditation" as defined in the Regulation. DIUS' current position is that the UK has a sole NAB for the UK, recognised by Government, and that accreditation is best effected through that NAB. The UK policy is to promote to business the use of laboratories, inspection bodies or certification bodies accredited by UKAS.*

3.2.2 Accreditation and non-harmonised standards

Q How will this regime apply to accreditation to standards which are not harmonised European Standards such as ISO 15189?

Q Will this regulation affect an organisation's ability to offer accreditation to non harmonised standards?

Q Can the NAB i.e. UKAS bid against conformity assessment bodies to provide or manage an accreditation service for a third party, against non harmonised standards?

Q Does UKAS' programme/scope address work on both harmonised and non harmonised standards?

- A. *The Regulation defines accreditation as attestation by a National Accreditation Body that a Conformity Assessment Body (CAB) meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in sectoral schemes, to carry out a specific conformity assessment activity, where a harmonised standard is one adopted by one of the European Standardisation Bodies, a CAB is a body that carries out conformity assessment activities (e.g. testing, calibration. etc) and conformity assessment is the process of demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled. The Regulation does not apply to non-harmonised standards.*

The Regulation does not prevent NABs (or any other organisation) offering accreditation to non-harmonised standards but such accreditation will not be covered by the Regulation. It is anticipated that UKAS will only wish to offer accreditation to non-harmonised standards in new areas of work where harmonised standards do not exist or where there are sector specific requirements. The expectation is that the standards will become harmonised or the work will be brought under the harmonised standards once the work has become established.

NABs cannot compete with the CABs they accredit and therefore NABs should not provide the same services as the CABs they accredit. However, this does not preclude a NAB offering accreditation using a non-harmonised standard as an alternative to a CAB offering conformity assessment activities when asked by a scheme owner or specifier to formulate a solution to meet their particular needs. We would not expect a CAB to offer accreditation (i.e. attestation of the competence of conformity assessment bodies) either to harmonised or non-harmonised standards.

We understand that ISO 15189² has been adopted by the European standardisation organisations already.

3.2.3 How the Regulation applies

- Q Can you please advise if the proposed legal framework for the provision of accreditation services across Europe will also apply to accreditation of healthcare organisations?

- Q Is this actually about how Accreditation Bodies work, or the interpretation of standards?

- Q ‘Products’, ‘Services’, and ‘Systems’ are all mentioned in the legislation, having all been added at various stages of the drafting, but still there is no mention of ‘Persons’ - so is the Regulation comprehensive?

- A. *The Regulation addresses accreditation and market surveillance, putting in place a legal framework for accreditation in the EEA. The Regulation defines accreditation as attestation by a National Accreditation Body that a Conformity Assessment Body (CAB) meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in sectoral schemes, to carry out a specific conformity assessment activity. DIUS therefore believes the Regulation to be comprehensive. If therefore a regulator in the healthcare sector decides to require CABs to be accredited against the harmonised standards then this Regulation will apply.*

- Q A proposed restriction on use of the word “accreditation” is not actually in the legislation, and not workable in the UK where it is widely used outside of the scope of the Regulation.

- A. *It is DIUS' view that the Regulation applies only to accreditation as defined in the Regulation. The Regulation does not therefore preclude organisations other than the National Accreditation Body (NAB) offering accreditation outside the definition contained in the Regulation. As was stated at the recent Open Day, DIUS continues to keep its accreditation policy under review and seeks to maximise the use of accreditation in the UK.*

² ISO 15189 is the International Standardization Organisation’s standard for use by medical laboratories in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognising the competence of medical laboratories.

Q The Regulation does not apply to CABs themselves. CABs are not required to seek accreditation at all.

Q. We need clarity on the statements made about what CABs “are required to do”. We are of the view that the new regulations place no requirements on CABs whatsoever. The requirements apply only to member states and to NABs. This needs to be stated unambiguously one way or the other.

A. *While the Regulation mainly concerns accreditation, NABs and Member States’ involvement, there is a clear impact on CABs and furthermore DIUS believes that Article 7.1 of the Regulation is directly applicable on CABs.*

Q The definition of conformity assessment in the final version of Article 2.12 in the Regulation has become reasonably consistent (although not identical) with the internationally accepted definition of that term in Clause 2.1 of EN ISO/IEC 17000:2004. In particular these two definitions in particular both extend to the conformity assessment of processes, systems, bodies and persons.

However, the title of the Regulation refers only to products, many of the “whereas” clauses also refer only to products, and some of the presentations on 3 December admitted or implied that the application of this Regulation in relation to categories other than products had not yet been thought through.

So can we be sure that the main Articles will eventually be applied to accreditation of the conformity assessment of processes, systems, bodies and persons? This question is not marginal but central, because the accredited certification of quality management systems (in particular) dwarfs all other accredited conformity assessment activities in Europe and worldwide.

A. *The Regulation applies to all accreditation activities in both the regulated and voluntary sectors and therefore covers the conformity assessment of processes, systems, bodies and persons.*

3.3 Notified Bodies

Q What will be the position of existing competent authorities that currently provide auditing of Notified Bodies, eg Medicines and Healthcare products Regulatory Agency, Maritime & Coastguard Agency, Vehicle Certification Agency etc?

Q Do the new regulations mean that all companies that offer “third party’ Lifting & Pressure inspections will have to be UKAS Accredited by statute to trade?

Q UKAS does not actually accredit Notified Bodies (NBs). Will the accreditation of NBs be made mandatory?

Q Is it likely that UKAS accreditation will become mandatory for all aspects of regulation in the future?

Q The use of the term “accreditation” with reference to EC Directives activities effectively makes it mandatory (via stakeholder perception) to be formally accredited (even though this is not the case).

A. *Accreditation remains voluntary unless required by specific legislation.*

Recital 12 however makes clear the aim to strengthen the preference for accreditation; that accreditation will be the preferred route for demonstrating the competence of conformity assessment bodies. This is a policy that HMG supports. Article 5.2 indicates the preference for accreditation as the means for verifying the competence of CABs that Member States select for the implementation

of Community harmonisation legislation. It will be up to National Authorities to decide when to make accreditation mandatory for specific legislation and where they do not, to justify that decision to the Commission.³

Q Are there appropriate competent authority guidelines specifying the appropriate criteria for accreditation of CABs?

A *There are guidelines for the assessment/accreditation of notified bodies for most directives. It is expected that the new framework for accreditation will make it easier for national authorities to use accredited conformity assessment in support of regulation without additional guidelines. However, where additional guidelines are required they will be drawn up either at the European or national level, as appropriate*

3.4 **Other**

Q. How will resistance to acceptance be overcome within the EU?

A. *There is no specific evidence as yet to resistance. Any resistance will need to be dealt with on a case-by-case basis between the Commission, Member State and appointed National Accreditation Body.*

Q Once this approach is fully in place what measures will there be to ensure that CE marked imports do in fact comply with the standards they claim?

A *The provisions on Market Surveillance and border controls in Chapter III of the Regulation are designed to enhance market surveillance across the Internal Market. The approach is based on member states having appropriate national systems, the necessary powers to deal with non-compliant goods, better cooperation between member states and with the Commission (including joint projects) and stronger measures to deal with non-compliant imports. The UK and other member states will need to take appropriate measures (both administrative and legal) to meet their legal obligations in these respects. BERR has created a strategic Market Surveillance Co-ordination Committee (involving the key market surveillance authorities and Government departments) to take this work forward. For more information please contact Jeff Asser (jeff.asser@berr.gsi.gov.uk).*

Q On what basis does DIUS consider there are clear benefits in having a single NAB?

A *Accreditation is the final authoritative level of ensuring that there is a uniform application of the standards assessing the competence of CABS in each market; to avoid what is essentially a regulatory function (albeit non mandatory) being driven by commercial motivations rather than national interests; and therefore avoid a further layer of assessment and surveillance at the accreditation level. Having more than one NAB undermines this position and adds variations in the way CABs are assessed.*

Q Validity of UKAS 'in-house' documents (LAB30 etc)

A *DIUS believes that documents providing clarification of the accreditation process will continue to be valid.*

Q What evidence is there to justify the statement that competition could lead to the commercialisation of accreditation - para 2.7?

A *Competition between accreditation bodies could lead to business considerations taking precedence over accreditation considerations. It is these pressures that the Regulation is designed to prevent.*

³ EC Decision 768/08 on a common framework for the marketing of products says in Article R14: Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation EC 765/08. The Decision makes clear its intent in Article R23.4: "Where a notification is not based on an accreditation certificate as referred to in Article [R22(2)], the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article [R17]."

- Q Moving forward: the need for consultation and partnership - the element of the regulation specifically concerning accreditation was added with little or no consultation with organisations such as the IIOC, which acts as a voice for a significant share of the market. Concern has been expressed that the UK has adopted a negotiating position which fundamentally changed the basis of the documentation provided for the original consultation. We would therefore welcome reassurance regarding the opportunities we may expect in the future to be able influence its interpretation across the market.
- A *The information pack circulated makes clear the level of consultation undertaken which, given the rapidly changing nature of the negotiation, DIUS believes to have been adequate. We have always endeavoured to keep stakeholders abreast of developments and allow them to influence interpretation and we will continue with this policy. Stakeholders should also bear in mind that negotiations on the Regulation involved 27 Member States and such extended interest was bound to result in some compromise. That said DIUS believes HMG, in its negotiations, was successful in consolidating the UK accreditation system in European law, which has always been its publicly declared objective.*

4.0 Glossary

| <u>Acronym - Term</u> | <u>Explanation</u> |
|------------------------------|---|
| AB | Accreditation Body |
| ANAB | ANSI-ASQ National Accreditation Board |
| Blue Guide | EU Commission publication: Guide to the implementation of directives based on the new approach and the global approach |
| CAB | Conformity Assessment Body * |
| CB | Certification Body |
| DIUS | Department for Innovation, Universities and Skills |
| EA | European Co-operation for Accreditation EA is the European network of nationally recognised accreditation bodies located in the European geographical area. The EA missions consist in: <ul style="list-style-type: none">▪ defining, harmonizing and building consistency in accreditation as a service in Europe, by ensuring common interpretation of the standards used by its members;▪ ensuring transparency of the operations (including assessments) performed and results provided by its members;▪ maintaining a multilateral agreement on mutual recognition between accreditation schemes and reciprocal acceptance of accredited conformity assessment services and results;▪ managing a peer evaluation system consistent with international practices - EA as a region is a member of ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum);▪ acting as a technical resource on matters related to the implementation and operation of the European policies on accreditation. |
| EAAB | EA Advisory Board |
| EEA | European Economic Area |
| EU | European Union |
| Harmonised standard | A standard adopted by one of the European standardisation bodies * |
| HMG | Her Majesty's Government |
| IAF | International Accreditation Forum |
| IIOC | Independent International Organisation for Certification Ltd |
| ILAC | International Laboratory Accreditation Conference |
| ISO | International Organization for Standardization |
| KPI | Key Performance Indicator |
| MLA | Multi-lateral Agreement |
| MRA | Multilateral Recognition Arrangements |
| MoU | Memorandum of Understanding |
| NAB | National Accreditation Body * |
| NAO | National Audit Office |

| <u>Acronym - Term</u> | <u>Explanation</u> |
|------------------------------|--|
| NDPB | Non Departmental Public Body |
| Notified Body | Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a New Approach Directive. |
| Peer Evaluation | A process for the assessment of a national accreditation body by other national accreditation bodies. * |
| Regulation | In this document this EC Regulation 765/08 |
| SLA | Service Level Agreement |
| SME | Small and Medium Enterprises |
| SOGS | Senior Officials Group on Standardisation |
| UKAS | United Kingdom Accreditation Service - the UK's National Accreditation Body |

** Please see the specific definitions in Article 2 of Regulation 765/08*

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