The UKCA Regime

Department for
Business, Energy
& Industrial Strategy

Agenda

1. Extension of the UKCA ‘Standstill’ period (BEIS)

2. The Accreditation Process for becoming a UK Approved Body (UKAS)

3. BEIS' priorities over coming months: addressing CAB capacity and improving business readiness (BEIS)

4. Q&A

Businesses now have until 1 January 2023 to adopt the UKCA marking

Responded to feedback

Businesses continue to face challenges from the pandemic which has made preparation for the UKCA marking more difficult. We are extending the current standstill arrangement for the UKCA marking for most goods for a further year.

Extended standstill

We will extend standstill arrangements for all manufactured goods (except medical devices) until 31 December 2022. UKCA marking will then be compulsory to place goods on the GB market.

Continuing preparations

We will use this extension to continue supporting industry. We are working to increase UK and overseas preparedness through more detailed engagement and support. We will also work closely with CABs to increase capacity.

Timeline for implementing the UKCA Marking

1 Jan 2021
CABs can conformity assess for the UKCA marking.

From 1 January 2023
The UKCA marking will need to be used for most goods* from 1 January 2023.

Until 31 December 2023
For most goods, manufacturers can affix the UKCA marking on a label affixed to the product or on an accompanying document (exceptions listed on gov.uk).

From 1 January 2024
The UKCA marking must, in most cases, be affixed directly to products unless the legislation allows otherwise.

*The implementation timeline is the same for most products types, with the exception of medical devices

Department for Business, Energy & Industrial Strategy

Placing Goods on the NI Market

UK NI

- The Ireland/Northern Ireland Protocol is now in force. For as long as it applies, goods placed on the market in NI will need to meet relevant EU rules.
- The CE marking will continue to be the relevant marking for most goods. Manufacturers that self-declare for CE, can continue to do this when placing goods on the NI market.
- The CE marking will need to be accompanied by the UKNI marking when products have undergone mandatory third-party conformity assessment by a UK-based body. This is now the case, and this rule applies to existing stock that was not already placed on the market by the end of 2020 (if that existing stock was assessed against relevant EU rules by a UK Notified Body). **Goods with the 'CE UKNI' marking are not valid for the EU market.**
- The UKNI is never applied on its own. It always accompanies the relevant EU conformity marking.
- If a manufacturer uses an EU Notified Body, they will only need to use the CE marking.
- The UKCA marking alone will not be valid for the NI market.

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UKCA Marking and the role of UKAS

Applying for UKAS Accreditation

Paul Greenwood, UKAS Operations Director

28th September 2021

Introducing UKAS:
The United Kingdom's National Accreditation Body

- UKAS is the United Kingdom's National Accreditation Body, appointed by Government through the Accreditation Regulations: 2009 (S.I. 2009/3155)
- Regulation (EC) No. 765/2008 has been retained within the UK, but amended via GB RAMS (S.I. 2019/696)
- UKAS is a not-for-profit company, independent of Government but works under a Memorandum of Understanding with the Secretary of State for Business, Energy and Industrial Strategy.
- Accreditation in the UK is considered a public authority activity, and UKAS works in the public interest.
- UKAS is a full member of, and signatory to the mutual recognition agreements of:
  - European cooperation for Accreditation (EA)
  - International Accreditation Forum (IAF)
  - International Laboratory Accreditation Cooperation (ILAC)

The Road to UKAS Accreditation: The Application Process

- Visit the UKAS website for details: www.ukas.com
- Complete the application form relevant to your application. This will include details of what to submit, including your management system and proof of legal status,
  - Main Application Form (Information about your company)
  - AC Form specific to the applicable conformity assessment:
    - AC1 - Certification Body Accreditation Application Form
    - AC2 - Inspection Body Accreditation Application Form
    - AC4 - Testing Laboratory Accreditation Application Form
  - F044 - UKAS Agreement
  - F378 - Confidentiality Waiver for Approved Bodies
  - Application Fee - £1,500.00 + V.A.T.

In parallel, applicants are required to notify the relevant department responsible for designating Approved Bodies of their application for UKAS accreditation for the purposes of becoming appointed as an Approved Body

The Road to UKAS Accreditation: The Assessment Process

- When an application has been received, a UKAS Assessment Manager will be appointed to assist you through the application and assessment process.
- The Assessment Manager will be responsible for appointing a technically competent assessment team
- Preassessment Visits – These are not mandatory, but applicants new to UKAS and accreditation are advised to have one as they can save time and money
- Desk Review – Prior to the assessment taking place a review of submitted documentation will be undertaken to ensure the applicant is ready to proceed.
- Initial Assessment – The initial assessment will be conducted by a Lead Assessor (normally the appointed Assessment Manager) supported by a team of qualified Technical Assessors / Experts.

The Road to UKAS Accreditation: The Assessment Process

- The initial assessment will begin with an opening meeting. The Lead Assessor will clarify the scope of the assessment and the criteria that the team will be using to conduct the assessment
- The assessment team may separate to examine the aspects of the application that have been assigned to them. Some of these may require assessment at clients sites, and may need to be conducted on different days to the Head Office visit
- The outcome of the assessment will be presented to the applicant in a closing meeting at the end of the visit. This will include a recommendation on whether accreditation can be offered
- Where areas are found not to meet the assessment criteria these will be discussed and raised as nonconformities. Nonconformities must be addressed before accreditation can be granted.
- Applicants are allowed up to 3 months to investigate the extent and cause of the nonconformity and then provide evidence to UKAS that effective corrective action has been taken.
- When all nonconformities have been addressed an independent UKAS decision-maker will make the final decision to grant accreditation.

The Road to UKAS Accreditation: The Accreditation Cycle

- Accreditation is granted by UKAS for a rolling four year cycle
- During this period the accredited organisation will be periodically assessed to ensure that the requirements for accreditation continue to be met
- Surveillance Visits – These visits are generally conducted annually, to review a sample of the policies, processes and procedures covered by the scope of accreditation. The first of these surveillance visits takes place 6 months after grant of accreditation.
- Reassessment Visit – In the fourth year of the cycle a reassessment is undertaken. This is designed to look at the full system in detail and determine that accreditation can be renewed for a further four-year cycle. There is no need to reapply.
- Extensions to Scope – At any time during an accreditation cycle a body can apply to extend its scope of accreditation to include new activities. A formal application is required

If UKAS becomes aware of any information that could have an impact in the performance of the organisation as an Approved Body then it shall inform the relevant Competent Authority

The Road to UKAS Accreditation: Available Resources

- Visit the UKAS website for information on the UKAS application process https://www.ukas.com/gain-accreditation/
- Visit .GOV.UK website for policy & guidance on becoming an Approved Body: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/960859/Guide-for-UK-conformity-assessment-bodies-2021.pdf
- UKAS Publication GEN 5 - Accreditation for the Purposes of Appointment as an Approved Body under the UKCA System https://www.ukas.com/wp-content/uploads/schedule_uploads/759170/GEN-5-Accreditation-for-the-Purposes-of-Appointment-as-an-Approved-Body-under-the-UKCA-System.pdf
- UKAS support and training events and courses – Specific courses for UKCA to be confirmed

Established in the UK

- Registered in Companies House or equivalent.
- Rights and Duties.
- UK public liability and professional indemnity insurance.
- Responsible for all contracts, CA activities, reports, certificates and decisions.
- Full operational control.
- Quality Management System applicable to UK.
- Full UK organisational structure.
- Key procedural documents in English.
- Identify Technical Management.
- Relevant contract with other CABs.
- Contracts, certificates and reports in like with UK law and in the name of the UKCA Approved body.
- Impartiality and Independence.

Technical Management

- Technically Responsible persons (technical management):
- Not expected to be permanently based at the UK office.
- Can be shared with other locations of the CAB.

BUT

When working on UKCA activities, must be effectively employed by the UK organisation.

UKAS

Thank you

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BEIS priorities: CAB Engagement

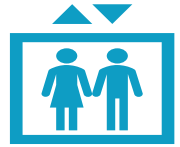
Our previous engagement with CABs identified insufficient CAB capacity to meet demand to test and certify some products for the UKCA mark. We have identified five sectors that are particularly affected:

Construction Products

Pyrotechnics

Cableways

Outdoor noise



Lifts

Working together with UKAS, we are undertaking a programme of engagement between September and October/November 2021 with UK CABs to better understand the barriers faced to increasing testing and certification capacity and plans for expansion.

This work will inform the development of potential government policy interventions, if required.

BEIS priorities: Business Readiness

In addition to our work on CAB engagement, we are working to increase business readiness for the UKCA marking amongst domestic and international businesses.

Our research suggests awareness in the UK is improving but we want to ensure businesses have taken action and improve awareness overseas too.

We have produced materials to help businesses understand the actions they need to take and are going to be running further webinars to cover key questions.

We would welcome support from CABs to engage with their clients and share materials and opportunities to attend events run by us with them.

Questions for CABs to consider:

We would appreciate your feedback on the following questions:

1) What barriers do you see to expansion/entry into testing and certifying for the UKCA marking?

2) Do you have any initial views as to what government could be doing to support CABs in those sectors where there is limited testing capacity?

3) Would CABs like to see more regular Government-CAB events in the future? What would you like to see from these?

We'll post a survey link in the meeting chat for you to follow.

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Questions from CABs

1. Has any decision been made on whether existing AVCP System 3 test reports issued by an EU Notified Body in support of CE marking under the CPR can be used as the basis of an equivalent test report issued by a GB based Approved Body in support of UKCA marking?
2. Does this "extension of the standstill period" mean a delay of 1 year on 'all' phases?
3. When will the Secretary of State for BEIS deliver the decision on legally mandated co-ordination activities for Approved Bodies?
4. How will BEIS ensure that HSE, Trading Standards, and other such bodies have joined-up thinking in their Market Surveillance Activities?
5. Will BEIS provide enhanced guidance for the definition of 'placement on the market', with examples and worked scenarios to support Economic Operators as the new 31 December date approaches?

Questions from CABs

6. The EU has changed how 'harmonised' standards are published, including a section for 'Restrictions'. This was not defined - will BEIS consult industry before changes to the Designation process are made?

7. Relating to the Pressure Equipment Safety Regulations - will guidance be issued on the process to be adopted for transferring Type Approval and Quality certification, NDT Personnel certification and permanent joining qualifications from EU Notified Bodies to UK Approved Bodies at the end of the Standstill period?

8. Are there any plans to introduce a fast-track process, or alternative less rigorous procedure, for UKCA approval of products which have already been CE certified?

Questions from CABs

9. Can you confirm that Approved Bodies would be expected to carry out their normal file review and examination procedures, and not just provide a certificate or a letter of approval based solely on a CE certificate?

10. Can you confirm applications for Approved Body status from European Certification Bodies are given the same level of scrutiny and obligations as UK Certification Bodies were subjected to by the European Commission?

11. Regarding the structure of Approved Body co-ordination groups, are there any plans for a Government supported Approved Body group in the PPE sector?

Thank you