



# **Memorandum of Understanding**

# between

# Department for Business and Trade

and

United Kingdom Accreditation Service

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# Memorandum of Understanding

#### 1 Purpose

- 1.1 To establish the way the parties to the Memorandum of Understanding (hereafter referred to as the "Memorandum") will work together to maintain and promote a strong national accreditation service in the UK.
- 1.2 To clarify the roles and responsibilities of the parties to the Memorandum.
- 1.3 The parties are the Secretary of State for the Department for Business and Trade (DBT) on behalf of Government as a whole, and the United Kingdom Accreditation Service (UKAS).

## 2 Background

- 2.1 UKAS was established in 1995 by the then Department for Trade and Industry (DTI), following a review of accreditation services in the UK, merging a number of public and private sector bodies to form a sole national body for the accreditation of conformity assessment bodies to carry out specific conformity assessment tasks. This status was recognised through a Memorandum of Understanding between DTI and UKAS.
- 2.2 The legislative framework for accreditation in Great Britain is set out in Regulation No. 765/2008 setting out the requirements for accreditation and market surveillance ("RAMS") which became incorporated into GB law by the EU (Withdrawal) Act 2018 and deficiencies [arising from the UK's exit from the EU] were corrected by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (Statutory Instrument 2019/696) (as amended). This is hereon referred to as "GB RAMS". In Northern Ireland, Regulation (EC) No. 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance (as it applies in EU law) will continue to apply (as a result of the Windsor Framework). It is hereon referred to as "RAMS NI". Both regulations require Government to appoint a single not for profit National Accreditation Body (NAB) to operate accreditation as a public authority activity.
- 2.3 DBT has appointed UKAS as the NAB for the UK via The Accreditation Regulations 2009 (Statutory Instrument: 2009/3155).
- 2.4 GB RAMS defines accreditation as "an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific conformity assessment activity".
  - RAMS NI defines accreditation as an "attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity".
- 2.5 As a component of the UK's National Quality Infrastructure, accreditation provides assurance of the competence and impartiality of Conformity assessment Bodies (CABs). The Government uses accreditation as the basis for the appointment of Approved and Notified Bodies and for other regulatory and policy purposes. It is vital that accreditation and UKAS provide robust assurance of Conformity Assessment Bodies' accredited activities.

## 3 Scope of activity

3.1 The activities for which UKAS is appointed by the Secretary of State as the sole national accreditation body under the terms of SI 2009/3155, this Memorandum, with the associated licensing agreement (in connection with the use of the National Accreditation Logo and

- Symbols) are set out in **Appendix 1**. Variations or amendments to the list will only have effect if agreed in writing between the parties hereto. UKAS will not undertake accreditation outside the scope of the activities in Appendix 1.
- 3.2 The activities not covered by RAMS NI or designated standards in GB, for which UKAS is recognised by the Secretary of State as the sole national accreditation body under the terms of this Memorandum and associated licensing agreement, are listed under 'Other requirements' in the table in Appendix 1. Variations or amendments to the list will only have effect if agreed in writing between the parties hereto.

## 4 Governance and accountability

- 4.1 UKAS will operate the accreditation activities for which it is appointed and recognised as the national accreditation body under SI 2009/3155, GB RAMS and RAMS NI. It will provide such information as is reasonably requested by the Secretary of State to demonstrate that it is operating in accordance with those instruments and this Memorandum.
- 4.2 UKAS will operate as a not-for-profit organisation as required by GB RAMS and RAMS NI. UKAS will ensure sufficient resources to carry out its functions as the UK's National Accreditation Body and to provide UK organisations with timely access to accreditation services.
- 4.3 UKAS will operate in compliance with BS EN ISO/IEC 17011 and other relevant national and international standards, regulations, guides and requirements, and with the terms of this Memorandum. It will be subject to periodic third-party audit for the purposes of demonstrating such compliance. UKAS will accredit against publicly available criteria agreed by the Secretary of State as set out in Appendix 1 to this Memorandum.
- 4.4 UKAS will in all its activities ensure that it takes fully into account the public interest in accreditation and will seek the involvement of a fair and acceptable balance of all relevant stakeholder interests in its work.
- 4.5 In all its work, UKAS will act in a manner consistent with its status as the UK's national accreditation body. It will maintain integrity and impartiality in the way it applies the relevant standards and judges conformance to those standards. It will not show undue preference, or exercise undue discrimination with respect to the provision of any service in relation to terms and conditions.
- 4.6 Both parties accept the need to work closely together to provide effective, efficient accreditation in the UK; to work together in the spirit of mutual trust, support and respect; and to ensure that when difficulties or differences arise they are addressed promptly, honestly and openly.
- 4.7 Both parties recognise the importance of consultation. All significant new initiatives and changes in working practices will be openly discussed between DBT and UKAS and, where appropriate, be open to wider consultation.

## 5 Fees and charging

- 5.1 UKAS (in accordance with SI 2009/3155) may charge fees to cover costs and other expenditure and will ensure that its fee charging arrangements are fair and reasonable. UKAS will publish details of its fees and charges.
- 5.2 Fee charging arrangements will be reviewed periodically by the UKAS Board.

## 6 Monitoring of UKAS

6.1 Appendix 2 to this Memorandum sets out the basis for the main ways for DBT to monitor UKAS as the National Accreditation Body as required in GB RAMS and RAMS NI.

#### 7 Appeals

7.1 UKAS in consultation with and with the approval of the Secretary of State, will maintain impartial and objective procedures and policies for the resolution of appeals made against its accreditation decisions. Such procedures and policies will, where appropriate, incorporate the provisions for appeals set out in SI 2009/3155.

#### 8 International

- 8.1 UKAS will promote international recognition for the UK system of accreditation. In its work, UKAS will seek to encourage the adoption of UK practice as the accepted international model.
- 8.2 UKAS will be the United Kingdom member of relevant international organisations on accreditation including the International Laboratory Accreditation Co-operation (ILAC), the International Accreditation Forum (IAF), relevant regional accreditation organisations (currently European cooperation for Accreditation EA) and, with the agreement of the Secretary of State, such other international accreditation organisations as may emerge. UKAS will subject itself to Peer Evaluations organised by the body recognised by the Secretary of State, which for the time being is EA.
- 8.3 The Secretary of State recognises UKAS as the UK body which will, where appropriate, negotiate mutual recognition agreements on accreditation with other national accreditation bodies. The Secretary of State will provide appropriate advice to UKAS in the negotiation of these agreements. Where the involvement of Government is required for the negotiation and signature of international agreements, UKAS will provide appropriate advice to the Secretary of State.
- 8.4 Notwithstanding the special position of UKAS within the UK, the Secretary of State will encourage where appropriate, recognition of certificates, awarded to CABs established outside of the UK, that are issued by those accreditation bodies with whom UKAS has agreed mutual recognition arrangements on accreditation when appropriate.
- 8.5 In carrying forward its international work under paragraphs 8.2 and 8.3, UKAS will ensure that it seeks and considers advice from a full cross-section of interests, including any relevant advisory committees established by UKAS. It will consult Government on all international accreditation issues where there is a significant Government or wider public interest involvement whether as a result of a request from Government or otherwise.

## 9 Support from Government

- 9.1 The Secretary of State will use appropriate means to support UKAS in the achievement of its objectives. The Secretary of State requires that where a UK CAB requests accreditation for the UK market, it shall do so from UKAS as the sole NAB for the UK. The Secretary of State recommends UK businesses, government and local authorities requiring third party conformity assessment services, including for public and private procurement, to source such services, where they exist, from conformity assessment bodies accredited by UKAS.
- 9.2 Where testing, inspection, certification or other conformity assessment activity that is covered by accreditation is required to demonstrate compliance with national legislation or guidance, or any similar rules or recommendations of any international institutions, Government will specify the use of laboratories, inspection, certification or other conformity assessment bodies accredited by UKAS. In line with UKAS' appointment as the sole national accreditation body for the UK pursuant to the Accreditation Regulations 2009, the Secretary of State will only recognise accreditation of UK CABs by UKAS in the voluntary and mandatory sectors.

- 9.3 The activities of UKAS will generally be self-financing from fees charged to customers. However, the Secretary of State will consider requests from UKAS for financial assistance to assist the initial establishment of new services, where these are required to support Government policy, and activities aimed at raising the awareness of accreditation, where it would be unreasonable for UKAS to meet these costs from its own resources; as well as requests from UKAS for financial assistance on a project specific basis in respect of UKAS' international activities under the International Programme.
- 9.4 Government representatives will participate as appropriate in the activities of UKAS, drawing upon the resources and expertise within Government to do so.
- 9.5 The Secretary of State, where practicable, will keep UKAS informed of changes and developments in Government policy in respect of accreditation, and will, wherever practicable, make changes following consultation with UKAS. The Secretary of State will keep UKAS informed of any intergovernmental discussions concerned with accreditation unless there are reasons of confidentiality for not doing so.

### 10 Support from UKAS

10.1 UKAS will provide all reasonable advice to the Secretary of State and other Government Departments on matters connected with accreditation, both on its own initiative and where requested to do so by Government including advice to Government on the selection of bodies for approval under the GB and NI regulations. UKAS will provide Government with access on request to its advisory committees for consultation purposes in connection with policy issues. UKAS will provide assurance to Government through the reporting mechanisms in Appendix 2.

#### 11 Status of the Memorandum

- 11.1 The Memorandum is an operational document and is not legally binding. DBT and UKAS have by signing the Memorandum agreed to use all reasonable endeavours to comply with the terms and spirit of the Memorandum.
- 11.2 The Secretary of State or a representative and UKAS will meet from time to time on an annual basis or sooner if required to discuss and review the operation of the Memorandum.
- 11.3 This Memorandum is effective from 14<sup>th</sup> September 2023. It may be amended by agreement or terminated by either party on 12 months' notice following full consultation with the other and, where UKAS is the recipient of such a notice to terminate, with each of UKAS' members for the time being. It may be terminated at any time by the Secretary of State for a breach of its provisions provided that the Secretary of State has informed UKAS of the nature of the breach and given UKAS a reasonable opportunity for the breach to be remedied.
- 11.4 This Memorandum may be terminated immediately upon the termination of the separate and legally binding agreement governing the use by UKAS of the Crown symbol.

Signed by,

Craig Watson

Deputy Director, DBT

C. Water

Signed on 14<sup>th</sup> September 2023, on behalf of THE SECRETARY OF STATE FOR BUSINESS AND TRADE

Signed by,

Matt Gantley

Chief Executive, UKAS

Signed on 14<sup>th</sup> September 2023, on behalf of UNITED KINGDOM ACCREDITATION SERVICE

# **Appendix 1: Standards Included in the MoU (2023)**

In accordance with paragraph 3.1 and 3.2 of this Memorandum, the activities for which UKAS is recognised by the Secretary of State as the sole national accreditation body under SI 2009/3155 and the terms of this Memorandum and associated licensing agreement are set out in this Appendix. Variations or amendments to the list will only have effect if agreed in writing between the parties hereto.

UKAS is appointed as the sole UK national accreditation body to undertake accreditation activity against the standards listed below:

| Standard Against Which Accreditation<br>Activity is Undertaken To Assess<br>Competence                              | GB<br>Designated<br>Standard <sup>1</sup> | EU<br>Harmonised<br>Standard in<br>NI | Other<br>Requirement |
|---|---|---------------------------------------|----------------------|
| ISO 14065: The accreditation of greenhouse gas validation and verification bodies                                   | No  | Yes                                   | Yes                  |
| ISO 15189: The accreditation of medical laboratories  | Yes                                       | Yes                                   | -                    |
| ISO 15189 in conjunction with ISO 22870: The accreditation of point-of-care testing providers                       | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17020: The accreditation of inspection bodies   | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17021-1: The accreditation of certification bodies for the certification of management systems <sup>2</sup> | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17024: The accreditation of certification bodies for the certification of persons                           | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17025: The accreditation of testing (including sampling) and calibration laboratories                       | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17025 in conjunction with ISO 15195: The accreditation of medical reference measurement laboratories        | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17029: The accreditation of validation and verification bodies  | Yes                                       | Yes                                   | -                    |
| ISO 17034: The accreditation of reference material producers  | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17043: The accreditation of providers of proficiency testing schemes  | Yes                                       | Yes                                   | -                    |
| ISO/IEC 17065: The accreditation of certification bodies for the certification of products, processes and services  | Yes                                       | Yes                                   | -                    |

| ISO 20387: The accreditation of biobanks  | No | No | Yes |
|---|----|----|-----|
| QSI standard (previously known as the ISAS standard): The accreditation of imaging services                           | No | No | Yes |
| IQIPS standard: The accreditation of physiological diagnostics services   | No | No | Yes |
| BS 70000: The accreditation of medical physics, clinical engineering and associated scientific services in healthcare | No | No | Yes |

# Notes:

<sup>1</sup> UK designated standards can be found on <a href="https://www.gov.uk/guidance/designated-standards">www.gov.uk/guidance/designated-standards</a>

**<sup>2</sup>** A complete list of management system certification standards and normative documents covered under UKAS accreditation is maintained on the UKAS website: <a href="https://www.ukas.com">www.ukas.com</a>

# **Appendix 2**

### DBT monitoring of UKAS as the NAB

#### Introduction

In accordance with paragraph 4.1 of this Memorandum and as referenced in paragraph 6.1 UKAS will provide such information as is reasonably requested by the Secretary of State to demonstrate that it is operating in accordance with GB RAMS and RAMS NI (as applicable).

#### **Annual Priorities**

Each year, DBT ministers will agree and set UKAS a number of annual priorities reflecting current departmental and governmental priorities. UKAS will provide updates on these priorities regularly at each quarterly meeting, the six-monthly ministerial meeting and report on these priorities at the end of each financial year.

#### **Monitoring and Reporting**

UKAS will monitor and report to DBT (on behalf of Government) on agreed activity in relation to the standards shown in appendix 1. The activities to be reported for relevant sectors, standards or legislation will be specified and reviewed between DBT and UKAS periodically. Issues that may be the subject of reporting include:

- Changes to CAB accreditation status.
- Significant non-conforming work notifications to UKAS and resulting actions undertaken by CABs and UKAS.
- Complaints about/from CABs.
- Appeals.
- Bi-lateral meetings between UKAS and regulators/policyholders whose legislation requires the use of accredited conformity assessment.

UKAS will provide to DBT the following documentation, where relevant within 10 working days of publication:

- UKAS Annual report and accounts;
- a bi-annual summary report on appeals and complaints received and customer satisfaction data; and
- advance notice of changes to fees and charges.

In addition to requesting written information DBT will monitor UKAS through:

- regular meetings;
- participation in UKAS activities; and
- independent reviews.

#### Regular meetings

Regular meetings between DBT and UKAS will be conducted including the following:

- Meetings to discuss progress against government priorities, challenges and key areas of focus, on a 6 monthly basis between the Minister and UKAS Chair and CEO.
- Meetings to discuss strategic priorities and performance between OPSS and UKAS executive leadership on a 6 monthly basis.
- Quarterly meeting between UKAS and OPSS, focusing on key progress and updates. Chair alternating between OPSS Deputy Director and UKAS CEO. UKAS to report on progress against government priorities, delivery of activities funded by Government via the annual

contract, customer complaints and action taken, and other areas of joint interest. OPSS Deputy Chief Executive to attend twice yearly.

Items that will be discussed at regular meetings may include: UKAS business performance (Balanced Score Card); business plans/strategic objectives and accounts; appeals; complaints; customer satisfaction; possible expansion into new areas for accreditation; SME support, developments in government policy; DBT assistance; information received from other government departments; the international accreditation infrastructure.

DBT will also regularly meet representative bodies whose members are accredited by UKAS or are users of accredited conformity assessment to obtain feedback.

#### Participation in UKAS activities

DBT will participate directly as a UKAS Member e.g. attending UKAS AGMs, as a member of the UKAS Policy Advisory Council and Forum; and any other relevant activity that is established in the future.

#### Independent reviews

UKAS will provide DBT with a copy of the Executive Summary of the European co-operation for Accreditation (EA) Peer Evaluation report on UKAS.

When EA peer evaluates UKAS, DBT may ask the evaluation team to review, or audit, aspects of UKAS not normally covered by a Peer Evaluation.

DBT may employ a third party independent organisation to review aspects of UKAS' performance.

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