

# **Risk-Based Approach to Assessments**

# **Customer Webinar**

# **Frequently Asked Questions**

## **Pilot Programme**

# Q. How long will the pilot programme run?

A. The pilot programme will run from Early-2021 to Mid-2024. The pilot is broken down into several stages according to Sector and further details on the pilot programme are available in the Terms of References and Information Pack provided.

Kindly note that the Data Collection Phase will run in its current guise for the 21-22 Financial Year only. In subsequent phases, the data collection and implementation phases will be run in parallel. Further details will be provided in due course.

# Q. If it is a pilot programme can I opt out?

A. Yes, Customers will be provided with the opportunity to opt out of the pilot. Further details are available in Annex 1 of the Terms of Reference. UKAS would encourage all customers to take part in the pilot programme as this will help us to ensure that we design and develop and effective Risk-Based approach. This approach will become standard for UKAS in the future.

# Q. Will the approach be rolled out to cover all areas UKAS accredits?

A. Yes, UKAS aims to roll out the Risk-Based Approach to all areas of the business should the pilot prove successful. Announcements will be made as sectors and Standards are added to the pilot programme

## **Data Gathering & Sharing**

## Q. What additional information do I need to supply for the Risk Evaluation?

A. Customers should not need to supply any more information to support the risk evaluation than they currently do.

## Q. Will UKAS release data on the number of customers in each monitoring group?

A. UKAS will not release information on the risk evaluation outcomes for individual customers. However, anonymised grouped information may be provided as part of the communication of the conclusions of the pilot programme.

# Q. Will UKAS share information or the outcome of evaluations with regulators and/or third parties?

A. UKAS continues to treat all information gathered as part of the accreditation process as confidential. We will not share information with external parties beyond the terms set out in the UKAS Agreement and any associated confidentiality waivers already entered into by the customer.

## **Assessment Process**



A world of confidence

# **Q.** How will the Risk Evaluation affect the date of my next assessment and the lead times involved?

A. The outcome of the evaluation will be discussed at the closing of your current assessment, which will include the expected date of your next assessment. The lead up timeframe for the assessment will remain unchanged. During the initial stages of the pilot we will not be confirming the date of the next assessment. This is to allow us to refine the evaluation matrix with the initial data set and ensure that there is minimal chance of change to the communication outcome

# Q. What are the Cost implications of the shift to a Risk-Based approach?

A. As the evaluations will be conducted as part of the assessment, UKAS does not anticipate any additional assessment effort will be required to complete the evaluation process during the pilot and will therefore not levy additional fees for administering the process.

The implementation of the monitoring outcome could affect the cost of accreditation, further details are included in the Terms Of Reference.

# Q. What happens if I need an Extension to Scope?

A. The Extension to Scope process will not be affected by the introduction of a Risk-Based approach. Requests for Extensions continued to be processed in the standard manner.

## Q. How will a flexible scope impact on our Risk Evaluation?

A. A flexible scope may increase the level of complexity involved; however it is not expected to have a significant effect on the outcome of the Evaluation.

## **Medical Laboratory Customers only**

## Q. When will the Medical Laboratory pilot start?

A. UKAS aim to start the pilot with the Medical Laboratory customers in Mid-2021. Customers will be notified once a start date has been identified

**Q.** How will the planned update to ISO15189 be affected by a Risk-Based Approach / How will UKAS include Risk-Based assessment requirement with planned updates to ISO15189? A. UKAS anticipates the planned updates to ISO15189 will include reference to and encourage Accreditation bodies to take a Risk-Based Approach to Assessment.

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