



Medicines & Healthcare products
Regulatory Agency

Contract Direct Award Recommendation

Project Title: Accreditation Service

Supplier: UKAS

Project Ref: 4289

Direct Award Ref: DA2020-001

Submitted By:	Caroline Edmonds
Value:	£75,000 (for 3 years)
Date:	31 st January 2020
Status:	Final
Version:	1.0

Template Version: 1.0

Author: Bill Martin, Head of Procurement, Finance and Procurement

Effective Date: 17th September 2018

Review Date: 9th February 2021

1 Introduction

This Contract Direct Award Recommendation is to cover a 36 month period with the option to extend for a further 2 x 1-year period starting immediately. The requirement is for maintenance of ISO 17025 Accreditation which is required annually.

1.1 .

UKAS Accreditation for control testing laboratories is a statutory requirement.

UKAS Accreditation to ISO 17025 enable NIBSC to continue to provide 'testing services to assure the quality of biological medicines'

Only UKAS can provide this accreditation service

Maintaining UKAS Accreditation to ISO 17025 has the following benefits

- Ensures delivery of MHRA and NIBSC objectives – Quality certification.
- Demonstrates NIBSC's competency, impartiality and performance capabilities as an approved evaluator.
- Confirms NIBSC has been assess and approved against International agreed Standards and EU Directives.
- Ensures NIBSC can continue to provide 'testing services' for batch release therefore safeguarding Public Health.

Ensures the continuity of accreditation

2 Justification for use of the negotiated procedure without prior publication

It is proposed to direct award this contract under the following section of the PCR2015, Regulation 32 32(2)(b) Where the works, supplies or services can be supplied only by a particular economic operator for any of the following reasons:

- (i) ~~the aim of the procurement is the creation or acquisition of a unique work of art or artistic performance,~~
- (ii) competition is absent for technical reasons,
- (iii) the protection of exclusive rights, including intellectual property rights

2.1 UKAS are the United Kingdom Accreditation Service, i.e. they are the only body licenced in the UK to perform this function.

3 Costings

Item	Cost	Years Required	Total	Notes
Cost of Purchase (Capital Cost)	25 000 per year		75 000 per 3 years	Estimation based on planned activities and 2019 prices

Item	Cost	Years Required	Total	Notes
Maintenance / Servicing	n/a	n/a	n/a	n/a
Operate Costs / Consumables	n/a	n/a	n/a	n/a

4. Approvals

4.1. Agency approvals

What approvals have already been made through Agency business processes.	This form. Signed UKAS agreement
Business Case Ref number	N/A
Financial limits and restrictions	N/A

4.2. Cabinet Office Controls

Do CO Controls apply? (See SOP on INsite)	No
If yes which control applies?	N/A
Control Ref number	N/A
Financial limits and restrictions	N/A

4.3. Proposed Length of Contract

Initial Contract: 3 Years

Potential Extensions: 5 x 1 year extensions

4.4. Terms and Conditions of Contract

T&Cs will be standard MHRA T&Cs for services.

5. Savings

Savings are a mixture of C1 and NC4. NIBSC cannot perform certain income generating functions without this contract.

Savings Type

Operational Transformation Benefits Definition				Equivalent Definition(s) in Bravo
Benefit Type	Benefit Category	Ref	Investment in the project or programme will ...	
Cashable	Revenue Increase	C1	... result in MHRA receiving more income	• n/a
Non-cashable	Risk Mitigation	NC4	... measurably reduce the likelihood or impact of documented risks	• Quality increases

Operational Transformation Benefits Definition				Equivalent Definition(s) in Bravo
Benefit Type	Benefit Category	Ref	Investment in the project or programme will ...	
				<ul style="list-style-type: none"> • Rationalisation Savings

6. Approvals

Name	Position	Signature	Date
Marie Donatantonio	SRO		31 st Jan 2020
Catherine Norris	Procurement Representative		7 th Feb 2020
Jennifer Sandle	Senior User/Contract Owner		31 st Jan 2020
Aneta Stranc	End User		31 st Jan 2020