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**United Kingdom-Potters Bar: Repair and maintenance services
2020/S 159-389127**

Prior information notice

This notice is for prior information only

Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1) Name and addresses

Official name: MHRA Buyer Organisation

Postal address: South Mimms

Town: Potters Bar

NUTS code: UK UNITED KINGDOM

Postal code: EN6 3QG

Country: United Kingdom

E-mail: purchasing@nibsc.org

Telephone: +44 1707641000

Internet address(es):

Main address: <http://www.nibsc.org>

I.2) Information about joint procurement

The contract is awarded by a central purchasing body

I.3) Communication

Additional information can be obtained from the abovementioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at: www.mhra.bravosolution.co.uk

I.4) Type of the contracting authority

National or federal agency/office

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title:

Filter Integrity and Environmental Performance Testing

Reference number: P5721

II.1.2) Main CPV code

50000000 Repair and maintenance services

II.1.3) Type of contract

Services

II.1.4) Short description:

The Agency will issue a set of conformance requirements to be used as the basis for the service agreement for the testing and environmental performance testing for all the HEPA filter systems within the Agency site.

II.1.5) **Estimated total value**

Value excluding VAT: 370 000.00 GBP

II.1.6) **Information about lots**

This contract is divided into lots: no

II.2) **Description**

II.2.1) **Title:**

II.2.2) **Additional CPV code(s)**

50000000 Repair and maintenance services

II.2.3) **Place of performance**

NUTS code: UK UNITED KINGDOM

Main site or place of performance:

NIBSC Site, Hertfordshire, ENGLAND, EN6 3QG.

II.2.4) **Description of the procurement:**

OJEU tender will be formally published within 12 months of this prior information notice.

II.2.14) **Additional information**

II.3) **Estimated date of publication of contract notice:**

11/08/2021

Section IV: Procedure

IV.1) **Description**

IV.1.8) **Information about the Government Procurement Agreement (GPA)**

The procurement is covered by the Government Procurement Agreement: yes

Section VI: Complementary information

VI.3) **Additional information:**

Title: Specification for Environmental Performance and Filter Integrity Testing

Purpose: To provide a specification that is to be used as the basis for the service agreement to all the HEPA filter systems and Environmental performance testing within NIBSC.

Associated documents:

Work bench Document Serial No 6598 for contractor general requirements

Work bench Document Serial No 6696 Replacement of HEPA Filters

Work bench Document Serial No 2709 Procedure for SSS Autoclave

Work Bench Document Serial No 1571 Maintenance, Testing, Validation and Cleaning of the UKSCB Cleanroom Suites

CBRM Folder with the title 'CBRM Clean Room Validation Summary' kept in room 1.24

CBRM Drawing for Pressure Cascade wide PDFM-CBRM-Air Flow-M5241.pdf

HPA/RA/02472 Maintenance and terminal HEPA filter change

HPA/RA/00601 Replacing Extract Filter HEPA CL4

BS EN ISO 14644-1:2015 specifies the classification of the related performance requirements for nine classes of environmental cleanliness.

BS EN ISO 14644-2:2015 specifies procedures for the monitoring of cleanroom performance related to air cleanliness by particle concentration.

BS EN ISO 14644-3:2019 Cleanrooms and associated controlled environments. Test methods. This British Standard has recently been updated and due to its length and complexity advice will be sought from our

specialist contractor to see if and how it impacts this document. A change request will be raised once the full implications are known.

BS EN 12469:2000 Biotechnology. Performance criteria for microbiological safety cabinets BS EN ISO 14698 -1:2003 Cleanrooms and associated controlled environments. Biocontamination control. General principles and methods

BSRIA Application Guide AG 3/89.3 'Commissioning Air Systems, Application procedures for buildings'.

This specification should be used as a minimum requirement and any additional recommended works should be agreed between NIBSC and the service provider.

The specification will cover the filter part of the system and a current equipment list will be attached to this specification if applicable (Equipment list attached YES/NO, delete as necessary).

The services required are:

Scheduled site/service visits and tests — to carry out routine and planned preventative maintenance (PPM) and testing schedule. (Completed certificates/service sheets of examination to confirm this) The service will be carried out to the appropriate British Standard for each area.

Health and safety:

Issued

9 December 2019

The correct PPE must be worn when removing installed HEPA filters and NIBSC policy adhered to for the bagging and preparation for autoclaving, prior to disposal.

Care must be taken when working at height, the most suitable access equipment must be used, as well as taking all other precautions associated with working at height. The service supplier must ensure that health and safety is adhered to and to implement safe working practices at all times when working within the institute. The service supplier is required to keep up to date with any changes of legislation within the industry that may affect their responsibilities to carry out the service level agreement. The service supplier must ensure that any service engineers attending site are fully trained and competent to carry out their duties in a safe and controlled manner.

Planned maintenance, service and testing cleanroom:

BS EN ISO 14644-1:2015 specifies the method of classification for nine classes of environmental cleanliness by the use of discrete particle counters.

BS EN ISO 14644-3:2019 specifies test methods for designated classification of airborne particulate cleanliness and for characterising the performance of cleanrooms and clean zones. Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational.

EU GMP, Amendment to Annex 1 (March 09) specifies the acceptance criterion

VI.5) **Date of dispatch of this notice:**

13/08/2020