

MHRA

# UKSCB Environmental Monitoring System (EMS) Replacement

Project No: Replacement Equipment/UKSCB EMS Replacement

MHRA  
8-8-2022

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# **Works Specification**

## **Works Information**

The present EMS is a ring-fenced system using a Trend 963 software operator interface and IQ251 Controllers and is installed for use in the UK Stem Cell Bank (UKSCB). Trend 963 software has only limited support as it is no longer being developed, the IQ251 Controllers are no longer manufactured so are becoming increasingly difficult to source in the event of failure.

## **1 Description of the works**

The intention is to replace the present EMS with a suitable system. It is anticipated that the field wiring and tubing including the sensors and components can be kept. The panels housing the present IQ251 Controllers located in the plant room are in good condition and can be utilized for the replacement controllers.

The Contractor will submit a tender price for the full cost of migration including all validation work to include installation and operational qualifications (IQ, OQ) and assist with developing a robust performance qualification (PQ) process to ensure the UKSCB meets its licensing requirements, the work will be carried out during the SLA period in late November and December 2022.

It is anticipated that the replacement EMS will be able to do all the current functions undertaken at present particularly in respect to user requirements both for end users and engineers, if this is not possible an alternative solution must be provided for each instance and agreed with the projects team. Any improvements and opportunities can be outlined and will be a bonus for the installation.

A Maintenance Contract should also be priced separately and any work that will impact on the running of the facility will need to be scheduled for the two annual shutdowns (normally June and December)

## **2 Drawings and SOP's**

List the drawings and SOP's that apply to this contract.

02\_Description

03\_ Operating Procedures

05\_As Fitted Drawings

EMS Controller IOs

Typical Trend BMS Schematic pages

Cyber\_Security\_Assurance\_Questionnaire

UKSCB EMS Replacement Specification

UKSCB\_Quality\_Questionnaire\_for\_EMS\_(FEMS)\_tender

6598 - General Requirements for External Contractors Attending site

5820 Check list for computer software validation form

## **3 Specification**

For the Contractor to deliver the migration from the present system to the replacement the following requirements need to be met:

- The Contractor will initially work with the project engineer and in-house Trend team and UKSCB users to ensure that all aspects of the present EMS are ready to be migrated and devise a strategy for optimum migration.
  - Devise a strategy for user access to maximise the security of the system on migration
  - Provide proposals to optimise the graphics of any proposed system to utilise best practise to ensure visually impaired users are not excluded from using the system. It is expected that will be in design and have no or low-cost implications.
  - Devise a method of interfacing with a separate BMS system currently in use in the UKSCB. The Agency specialist Trend Contractor can be used to assist with this requirement.
  - Understand how the onsite engineer callout process works to replicate on the new software

- The successful Contractor must have previous experience of working on an equivalent facility and be able to provide references and proof.
- The Contractor will demonstrate how they intend to set up the installed software to allow multiple users to interrogate the system within allowed security access levels, the users will be a mixture of engineers, experienced operators, and lower-level users.
- The Contractor must demonstrate that they have a full understanding of the way the Trend system is presently set up on the NIBSC site so that the critical functions can be replicated on the new system including:
  - EMS pages set up on schematic pages
  - Alarm set up and handling including transmission paths as used by the present system
  - User interface
  - Password and security set up
  - Monitoring, recording, and archiving of collected data for critical equipment and areas
  - Understand the present system regarding IT and multi-user interface including engineer out of hours call outs.
  - The Quality Audited System used to monitor scientific equipment
- The Contractor must demonstrate how each aspect of the EMS system is replicated in the IQVision software with any enhancements or improvements highlighted. Any potential issues or problems should also be raised.
- Develop the most robust IT strategy to help prevent any interruptions to the EMS system and help with a disaster recovery plan. Any supplier must be prepared to work closely with the IT Team to deliver the required IT architecture and secured system). Connection to the Ethernet IT infrastructure must use CAT7a cable.
- Site specific training for different levels of operators must be allowed for on the new system
- The contractor will demonstrate how they intend to provide rapid support and fault rectification of any issues or problems caused by the replacement system including timescales.
- To meet our Quality requirements a software validation plan will be delivered (see Validation Plan Template Attached with the Tender) The successful supplier will assist with the implementation and development of this plan prior to work commencing.
- Due to the length of the project, it is important from an NIBSC point of view that both continuity of persons undertaking the work and costs are managed and maintained. Within the Atamis questions is an opportunity to explain your strategy in this regard.
- To comply with sustainability directives, the power consumption for all parts of the IT system must be documented including Controllers and PCs
- The current labels for equipment and parts of the system must be replicated in the new software.

#### **4 Maintenance and Service**

As well as tendering for the IQVision migration an option for the servicing and maintenance of the system starting after installation include the following:

- SLA area maintenance of the new EMS including calibration (meters must be calibrated to UKAS standards and three-point calibration is currently undertaken) for Temperature, Humidity, Pressure.
- Callout within specified response times.
- The successful contractor will be able to provide training as required at an agreed cost.

## **5 Constraints on how the Contractor Provides the Works**

### ***5.1 Permit to Work***

The Employer operates a permit to work system these include the following as required by the work: -

- Authorization to access
- General Permit to work

All permits will be issued as necessary by authorized staff. No work is to commence without the possession of the relevant permit to work. These must be returned to the issuer on completion of the works for filing.

There are no health risks to contractors' personnel from the Employers activities if the Employers controls are complied with fully.

### ***5.2 Programme of works***

Please supply a Gantt Chart Schedule in your tender return. This should show all lead times. It is preferable that this is supplied in Microsoft Project but an excel spreadsheet would be accepted.

### ***5.3 Design Change Post Contract Award***

Any change to this specification after the tender has been received and the contract awarded will be controlled using the NIBSC's Design Change form that is signed by both the Institute's project leader and the contractor's representative. The form will identify the change and its effect on costs and timescales. An example of this form can be found in the attachments

### ***5.4 Site Access***

Mon- Fri 08:30 to 17:15 (other hours by agreement with the Project Engineer)  
Sat & Sun With the permission of the Project Engineer

Access to the site will be via the main access to NIBSC, which is shared with the client's employees, and visitors. All vehicles will be stopped at the security cabin and all drivers will be required to comply with the client's security arrangements.

Any work outside of the above hours can be facilitated with agreement of the Project Engineer. After 7pm no work can take place unless security and PE have agreed to this.

### ***5.5 House Keeping***

Due to the clean environment required for the work of the institute, good housekeeping is always required. All waste material must be removed from site daily and storage for materials on site is not available.

### ***5.6 Confidentiality***

Contractors are expected to keep any information about the work of the Institute or staff always details totally confidential. The contractor is requested to sign a Confidentiality Agreement as attached and return with the Tender.

## **6 Services and other things provided by the Employer**

### **6.1 Services**

NIBSC will provide services including water, use of welfare facilities, and electricity.

### **6.2 Free issue items**

No Free issue items with this project

## **7 Location**

The site Address is:

- NIBSC Blanche Lane, South Mimms, Potters Bar, Hertfordshire EN6 3QG.

### **7.1 General**

The contractor is always to comply with the Institute's H & S guidelines while on site. The H&S advisor on site has responsibility for ensuring compliance on the Institute's behalf and will form part of the project team.

All contractor employees will be given the site induction when attending site for the first time. There will be further inductions for specific specialist areas as and when required. Prior to attending site there will be a one-off baseline Personal Security Standard check, this will be organised by the Project Engineer responsible for the work.

Should, as a result of the contract, an incident or accident occur to either a member of the Institute's staff, property or contractor's employees, the person responsible for you on site (generally the Project Engineer) must be informed as soon as possible after the immediate emergency has been dealt with. The responsible person will then inform the H&S team. Site rules, practices, and procedures to be established and enforced will include but not necessarily be limited to the following: -

- Contractors' personnel must comply fully with the client's security arrangements and procedures
- Operatives and visitors report to the site supervisor are inducted and sign in and sign out
- Smoking is not permitted on the site except in defined areas
- Radios and personal stereos are not permitted
- Personal protective equipment must be worn as required by their risk assessment
- Correctly rated and inspected electrical equipment are used where applicable

- Site Fire precautions and procedures are maintained by Contractor's personnel.

The Employer will continue to operate normally in the building. However, it will be necessary for some operational areas to be vacated for periods of time to allow works to be carried out. The Contractor will be required to liaise with NIBSC so that a program can be established to suit operational requirements. Access to all areas for Employer's maintenance personnel must always be maintained unless alternative arrangements have been made with the Project Engineer.

The Contractor must ensure that his operations do not pose any risk to the Employers personnel or visitors to the complex.

There are no health risks to contractors' personnel from the Employers activities if the Employers security controls are complied with fully.

### **7.2 Storage of materials and tools**

NIBSC is very limited on internal space and therefore all material and tools will need to be stored in an area designated by the Project Engineer.

### ***7.3 Stage handover and training***

If a project has one or more stages/phases, then we will require a/several stage handover/s. This will require O&M details to enable maintenance to add the details to the PPM system. Additionally, training will be required for the new plant/equipment.

NIBSC are interested in sustainability and environmentally friendly solutions. Please provide examples of where your company can provide increased energy efficiency.

### ***7.4 Site Survey***

All tenderers will be expected to carry out full site survey to verify the work required to fully comply with the scope of the specification. This is mandatory for all contractors tendering as non-compliance will result in tender disqualification.

### ***7.5 Welfare facilities***

The site has toilets, power and water which will be provided to contractors with the Employer's permission. The site also has a staff restaurant that the Contractors staff may use subject to persons being properly dressed (no bare torsos or shorts) and in clean and tidy clothing. We have first aiders on site.

## **Appendix A System Details**

See attached Tender documents for detailed information and overview