

**Programme CORTISONE**

**Laboratory Information Management System for Defence Medical Services’ Deployments and Operations.**

**Prior Information Notice and Invite to Market Interest Day**

Version: 0.1

Date: 13 January 2025

**Introduction**

1. Thank you for your interest in the CORTISONE Programme.
2. The objectives of this Prior Information Notice (PIN) are for the Authority to:
	1. better understand relevant LIMS providers and products that may solely or collectively provide the capability required,
	2. understand what the market can provide in relation to the services required,
	3. Invite the industry to a Market Interest Day to engage with the project team on the LIMS requirement.
3. Programme CORTISONE is seeking to integrate a number of Commercial Off the Shelf (COTS) products and services to provide an ecosystem of sub-systems that will constitute future UK Defence Medical Information Services (Med IS). The Programme is entering the Delivery Phase and intends to procure products to deliver a Laboratory Information Management System (LIMS) solution for Defence Medical Services (DMS) military deployments and operations.
4. DMS work closely with the Royal Navy, Army, and Royal Air Force to generate medical capabilities to support global deployments involving UK forces. These deployments can either be standalone or in partnership with NATO and key allies. They cover the full spectrum of UK Defence standing and contingent commitments.
5. Defence Pathology is a critical component of the healthcare provided to maintain the health and fitness of the deployed force. This is principally an Occupationally driven, General Practice led, Primary Care Service that includes Rehabilitation, Mental Healthcare, Occupational Health and Sexual Healthcare capabilities tailored to the size and composition of the deployed population at risk (PAR). For all specialities, the LIMS is the primary repository of data relating to testing and subsequent reporting.
6. In Defence Pathology, laboratory data is generated across four main areas (any future solution must cover each of these):
	1. **Blood Sciences**
		* Clinical Biochemistry
		* Haematology and Coagulation
	2. **Transfusion**
		* Blood Banking
		* Blood grouping and crossmatching
	3. **Microbiology**
		* Culture
		* Serology / Virology
		* Molecular diagnostics
	4. **Referrals**
		* Management of specimens referred to other laboratories for specialist testing unavailable in the deployed space for each of the above
		* Cellular Pathology specimen referral
		* Recording of results for specimens referred to other laboratories for specialist testing.
7. Defence Pathology operates overseas and maritime deployed pathology services on an as-required basis in deployable medical facilities ranging in size from small teams (single resus and surgical bed with no hold capability) through to full size field hospitals (up to 100 ward beds) as part of the DMS. The medical capabilities on deployments should be considered as a network providing care through fixed, mobile and peripatetic service delivery methods.
8. In addition, Defence Pathology personnel are located at four UK based locations (Centre of Defence Pathology, the Training School, and two Joint Hospital Group sites)
9. LIMS products for use in deployed theatres of operations should be able to operate with extended periods of poorly connected or dis-connected network availability and support digital integration in the following ways. Therefore, intermittent connectivity forms a core element of the Statement of Requirements.
10. Defence Pathology’s LIMS requirement will be hosted on DEFMED which is a hosting platform which is used to host Defence medical applications and clinical equipment. DEFMED provides server hosting, managed UAD and direct connection to the Authority network.
11. MedIS Project team will be hosting a Market Interest Day where the CORTISONE programme and proposed LIMS design will be shared with industry. Key details can be found below:
	1. Online Market Interest Day (To be hosted on: Microsoft Teams)
	2. Date: 5 Feb 2025 , Time is to be confirmed in the meeting invite.
	3. There will be an opportunity to present existing solutions, but this will be further explained in the meeting invites.
	4. The Market Interest Day will cover:
		1. Who we are,
		2. What we are looking for,
		3. Who the suppliers are,
		4. Duration of the requirement,
		5. Context around critical elements of the LIMS system and their feasibility,
		6. An opportunity for the industry to comment on the requirement through a Q&A session.

**Responding to this PIN**

1. Responding to this announcement is voluntary and does not start the official procurement process for the CORTISONE requirement. It should be noted that all information released in relation to this PIN is done so on a without commitment basis, is subject to change and does not signal the start of a formal procurement process. The CORTISONE team intends to provide further details of the requirement itself at the Market Interest Day. The programme team is intending to better understand the routes to market which could provide access to relevant products and services. Please may you contact UKStratComDD-CIS-ASD-MISEngage@mod.gov.uk by 17:00 GMT on 30 January 2025 to register your interest and provide contact details of no more than [3] individuals to attend the Market Interest Day. If you have any questions about the Market Interest Day, please email the Multiuser below and the project team will respond accordingly.
2. Should you have immediate questions about the LIMS specification below please also send these via email. Please note, the project team will collate these questions and provide a response to the most requested themes at the Market Interest Day.
3. Programme CORTISONE has issued this PIN to gain insight into the appetite of the industry around bidding for a LIMS procurement with the MOD. The Programme team would be grateful for any information you are able to provide.

**Annex A: High Level Statement of Requirements:**

| Requirement | Must Have / Should Have |
| --- | --- |
| Provide data management for the following:* Blood Sciences
	+ Clinical Biochemistry
	+ Hematology and Coagulation
* Transfusion
	+ Blood Banking
	+ Blood grouping and crossmatching
* Microbiology
	+ Culture
	+ Serology/Virology
	+ Molecular diagnostics
* Specimen Referrals
	+ Management of the referral of specimens for specialist testing unavailable in the deployed space for each of the above
	+ Cellular Pathology specimen referrals
	+ Recording of results for specimens referred to other laboratories for specialist testing
 | Must Have for all |
| Provide a two-step result validation system (technical validation and clinical authorisation) for all results | Must Have |
| Allow direct interfacing of Pathology analysers:* Fuji DryChem NX 500
* Fuji DryChem NX 700
* Aboott iStat 1
* Horiba Micros ES 60
* Yumizen H500
* Yumizen G200
* Biofire FilmArray (Biomerieux)
* Cepheid GeneXpert
* Bac T Alert 3D 60

With the option to add further analysers in the future on an as required basis.Use of bi-directional interfaces where applicable. | Must Have for all |
| Support BMS and Clinical decision making on result validation / authorisation through:* Reference ranges for all tests and danger limits where applicable
* Highlighting test results outside of reference range (and danger limits)
* Automated and / or pre-defined comments, free text comment entry for all results
* Automated validation of “normal” results (not currently used by Defence Pathology)
* Automated transfer of abnormal results to technical validation / clinical authorization queues
* Population of manual test worksheets / worklists
* Reflex testing (additional tests based on test results)
* Alerts, warnings, and notifications for users
 | Must HaveMust HaveMust HaveShould HaveShould HaveShould HaveShould HaveMust Have |
| Provide individual secure log-in for all users with a managed system of access levels | Must Have |
| Provide stock management functionality for blood banking, including:* Traceability records
* Product labelling (for issue)
 | Must Have |
| Allow for electronic reporting, including interim reporting. Electronic reports must be able to be transferred into the wider CORTISONE software suite  | Should Have |
| Allow for electronic order comms from wider CORTISONE software suite  | Should Have |
| Allow for printing of reports, including interim reports | Must Have |
| Allow Defence Pathology to remain compliant with BSQR and ISO 15189 | Must Have |
| Be compliant with and have associated evidence for DCB 0129 Clinical Risk Management | Must Have |
| Provide full functionality to the end user solely utilising a deployed local network (i.e. without connectivity to the UK). Please see Ref B for more information.  | Must Have |
|  Allow asynchronous / intermittent connectivity to a central data repository (hosted in the UK) referenced in Figure 1.  | Should Have |
| Allow Operations / Exercises to be uniquely identified, with all data relating to that Operations / Exercises being identified as such | Must Have |
| Allow for remote result validation / authorisation (when connectivity allows) | Should Have |
| Be capable of being run on a variety of hardware (e.g. laptops) and network configurations including Authority supplied and managed devices (Intel (R) Core (TM) i7-8665U CPU, 16GB RAM, Windows 10 Professional or similar). | Must Have |
| Maintain an auditable record of actions undertaken within the system | Must Have |
| The system must facilitate the future transfer of data to storage solutions, with an expectation of taking a standards-based approach  | Must Have |

**Please note:** This is a high-level requirement and does not cover the full extent of the specification, nor is this a finalised version and may be subject to change.

Figure 1: The interaction of LIMS with DEFMED and CORTISONE Ecosystem Data Storage components.

Glossary of terms associated with LIMS and Pathology

| **Term (Acronym / Abbreviation)** | Definition / Description |
| --- | --- |
| Analyser Interface | Connection between the LIMS and the laboratory analyser, may be bi-directional or unidirectional depending on the analyser |
| Bacteriology | Sub-speciality of microbiology that identifies bacteria, usually through culture |
| Blood Bank / Transfusion | Department that provides blood for transfusion and associated testing, can be a sub-speciality or sub-department of haematology in some labs but is often functionally separate |
| Blood Establishment | Entity registered with the MHRA to perform one or more of the following: manufacture, supply, store or provide blood or blood components for transfusion (CD Path is the MoD blood establishment). All UK blood banks are blood establishments. |
| Blood Safety and Quality regulations (BSQR) | Regulations on manufacture, supply and use of blood and blood components for transfusion in the UK  |
| Blood Sciences | Laboratory department that tests blood and other bodily fluids, usually consists of chemistry and haematology |
| Blood Tracking System | Usually refers to a system that assures the blood transfusion process from point of collection from the blood bank through to administration to a patient (i.e. within a hospital). Typically, this will include patient and product identification steps to prevent a patient from receiving inappropriate blood. As a supplier of blood for transfusion and as the entity that provides assurance for deployed blood banks, CD Path needs to track blood from point of collection from NHSBT through to final fate. |
| Cellular Pathology / Anatomic Pathology (Cell Path) | Study of tissues and gross anatomy, not a service provided by defence pathology |
| Clinical Biochemistry (Chemistry) | Pathology speciality that tests the liquid component of blood and other bodily fluids, usually forms part of blood sciences |
| Coagulation (Coag) | Usually a sub-speciality of haematology, provides testing related to blood clotting |
| Culture | Process of growing and identifying micro-organisms  |
| DCB 0129 | Clinical risk management documentation used to show an IT systems compliance with the provisions within the Health and Social Care Act as applied to a healthcare IT system supplier / manufacturer. See [here](https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems) for more details |
| DCB 0160 | Clinical risk management documentation used to show an IT systems compliance with the provisions within the Health and Social Care Act as applied to a healthcare IT system user. See [here](https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems) for more details. |
| Genomic / molecular laboratory | Testing of an individual’s genome for specific genes or markers, not a service offered by defence pathology |
| Good Automated Manufacturing Practice (GAMP) | The guidelines for IT system validation, which MHRA requires for all IT systems related to blood product manufacture and transfusion. (Specifically, GAMP 5) |
| Haematology (Haem) | Pathology speciality that tests the cellular components of blood and coagulation studies, usually forms part of blood sciences |
| (HECMS) | Healthcare Enterprise Content Management System |
| Integrated Clinical Environment (ICE) | Electronic order comms and result reporting system for Pathology. Can be cloud or software based and allows remote test requesting and result lookup. |
| ISO 15189 | International standard on medical laboratory quality and competence. Not mandatory for defence pathology, but we work to these standards whenever possible |
| Laboratory Information Management System (LIMS) | Used to manage and report all laboratory test data |
| Laboratory Information System (LIS) | Analogous to LIMS, but usually has a patient centred approach to lab data |
| Medicines and Healthcare products Regulatory Agency (MHRA) | Regulatory body that assures a blood establishments compliance with BSQR |
| Microbiology (Micro) | Laboratory department that identifies infectious organisms |
| Molecular diagnostics  | Process of identifying infectious organisms by detection of nucleic acids or other biomarker molecules (usually by PCR or similar technique) |
| Quality Management System (QMS) | System used to manage quality assurance in a laboratory – defence pathology uses a cloud-based system called iPassport |
| Serology | Sub-speciality of microbiology that uses blood tests to identify infectious organisms |
| Traceability - Blood | Requirement for records to be maintained covering all events relating to blood for transfusion from point of donation through to point of disposal or transfusion to a patient. Each organisation involved in the manufacture, supply, storage and use of blood for transfusion is responsible for maintaining records relating to their activities. |
| User Requirement Specification (URS) | Document describing the detailed requirements for a LIMS. Part of GAMP framework and forms the basis of the validation process. |
| Virology | Sub-speciality of microbiology that identifies viruses |