King Edward VII Memorial Hospital

Pathology & Food Water & Environmental Laboratory

LABORATORY QUALITY MANUAL

LAB-POL-12 V3

Chester Crowie (Pathology Laboratory Manager)

KEMH LABORATORY DEPARTMENT St Mary's Walk, Stanley

Table of Contents

1.0 Introduction

1.1 The King Edward VII Memorial Hospital (KEMH) laboratory department, comprising of both FIG Food Water and Environmental (FWE) laboratory and KEMH Clinical Pathology laboratories, is a multi-disciplinary facility providing services to the Health Professionals within the KEMH, external health care providers, FIG public sector services, private and commercial customers in the Falkland Islands.

1.2 The Clinical Laboratories provide a range of test investigations in Biochemistry, Haematology, Transfusion and Microbiology.

1.3 The Food Water and Environmental laboratory provides microbiological investigations (detection and enumeration) of water, food and food preparation environment samples. This laboratory is UKAS accredited as FWE, UKAS reference number 26971 and is compliant with ISO 17025:2017. The current schedule of accreditation and scope of tests can be found on the UKAS website (Search UKAS accredited organisations) and held in Q-Pulse as document FWE-REF42.

1.4 This document has been prepared by the Laboratory Management Team to represent the Quality Management System of the KEMH Laboratory Department, King Edward VII Memorial Hospital, Falkland Islands Government, and represents the laboratory's ability to execute its service provision in a manner which conforms with the requirements of BS EN ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories.

1.5 This document has been prepared to define the quality system, establish responsibilities of department and users affected by the system, and to provide general procedures and policy summary statements for all activities comprising the quality system. In addition, this manual is used for the purpose of informing our customers of the quality system and what specific process controls are effectively implemented to assure service quality.

2.0 Scope

2.1 The KEMH Laboratory Department Quality System applies to the testing of all samples within the laboratory facilities, and to the management of Point of Care Devices owned and deployed by the KEMH Laboratory Department.

2.2 This document applies to all services provided by the KEMH Laboratory Department within DHSS property.

3.0 Definition & Abbreviations

3.1 CA: Competent Authority

3.2 CAPA: Corrective Action/Preventative Action

3.3 CMO: Chief Medical Officer

3.4 DHSS: Dept. Health & Social Services

3.5 DoA: Dept. of Agriculture

3.6 FIG: Falkland Islands Government

3.7 F.W.E/FWE: Food, Water & Environmental laboratory

3.8 KEMH: King Edward VII Memorial Hospital

3.9 MOU: Memorandum of Understanding

3.10 MR: Management Review

3.11 NC: Nonconformance – An aspect of the Quality System that does not meet the defined standards set out in this quality manual.

3.12 QA: Quality Assurance

3.13 QC: Quality Control

3.14 QM: Quality Manager (laboratory)

3.15 QMS: Quality Management System

3.16 SLA: Service Level Agreement

4.0 Laboratory Structure (ISO 17025 & 15189 section 5)

4.1 The KEMH Laboratory Department is managed and resourced as part of the Falkland Islands Government Department of Health and Social Services. As such the Falkland Islands Government is legally responsible for the activities carried out within the department.

4.2 The Director is ultimately responsible for the service provisions of the DHSS and ensuring those are appropriately resourced.

4.3 Clinical direction and Public Health are led by the CMO.

4.4 Operational management of the KEMH is the remit of the Hospital Manager.

4.5 Operational and Technical management of the KEMH Laboratory Department is the duty and responsibility of the Laboratory Manager. The Laboratory Manager is responsible for; providing a range of clinical, food and water test services to meet the Falkland Island's needs and demands, ensuring efficient and effective use of available resources, line management of staff, staff training, delegated financial authority, scientific leadership and departmental Health & Safety standards. The Laboratory Manager is the designated deputy for the Quality Manager.

4.6 The Laboratory Quality Manager is responsible for the QMS of the laboratory including; maintenance, monitoring and improvement of the QMS, adherence to requisite ISO standards (ISO 17025 and ISO 15189), maintenance monitoring and improvement of document control systems and processes, regular reporting to the laboratory management review board and is the first point of contact for liaising with external accreditation bodies. The QM is the designated deputy for the Laboratory Manager.

4.7 The laboratory staffing structure is shown in Figure 1.

4.8 The DHSS reporting structure is shown in Figure 2.

4.9 FIG structure is shown in Figure 3.

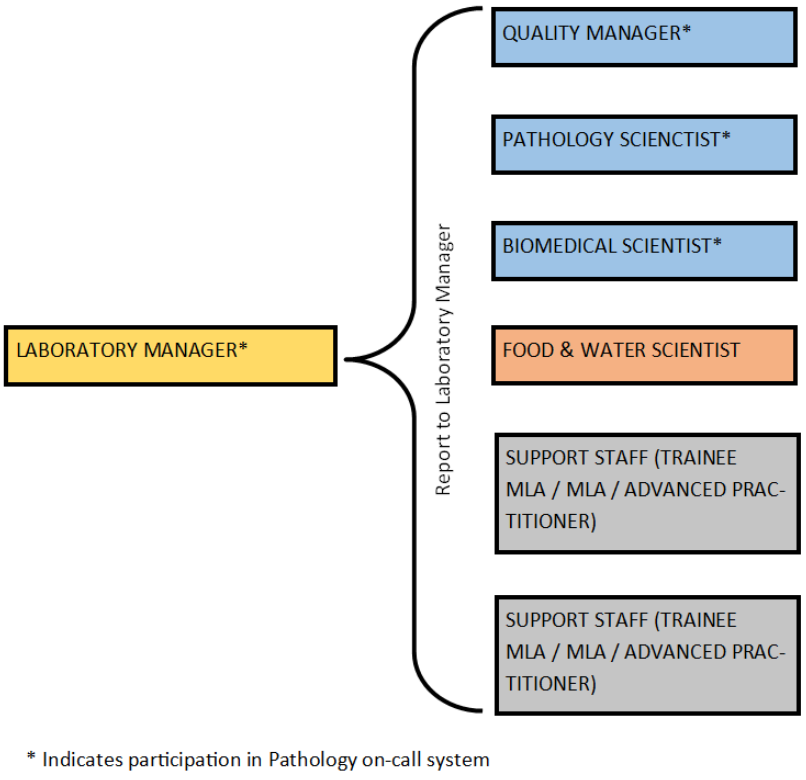

Figure 1: KEMH Laboratory Department Establishment Reporting Structure

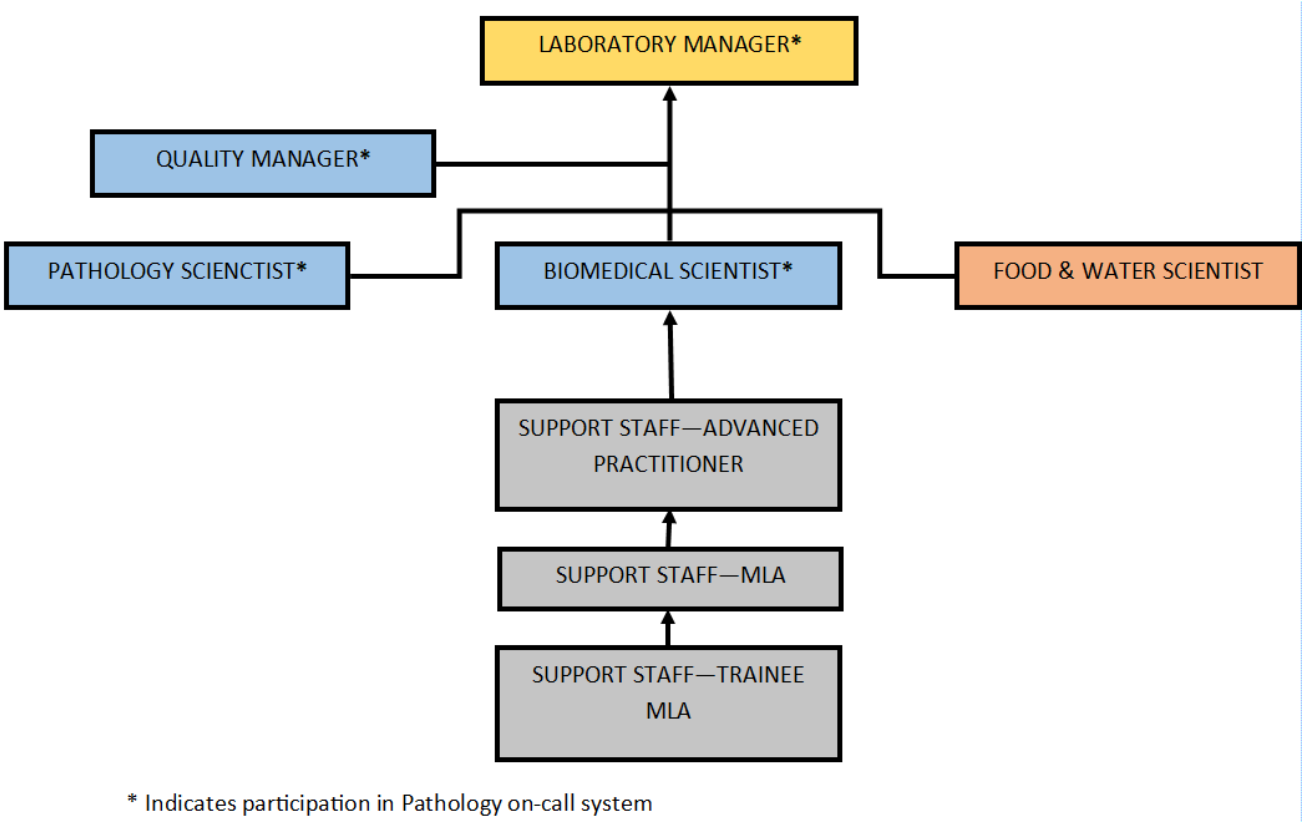

Figure 2: KEMH Laboratory Department technical escalation structure based on Knowledge, Skills and Experience

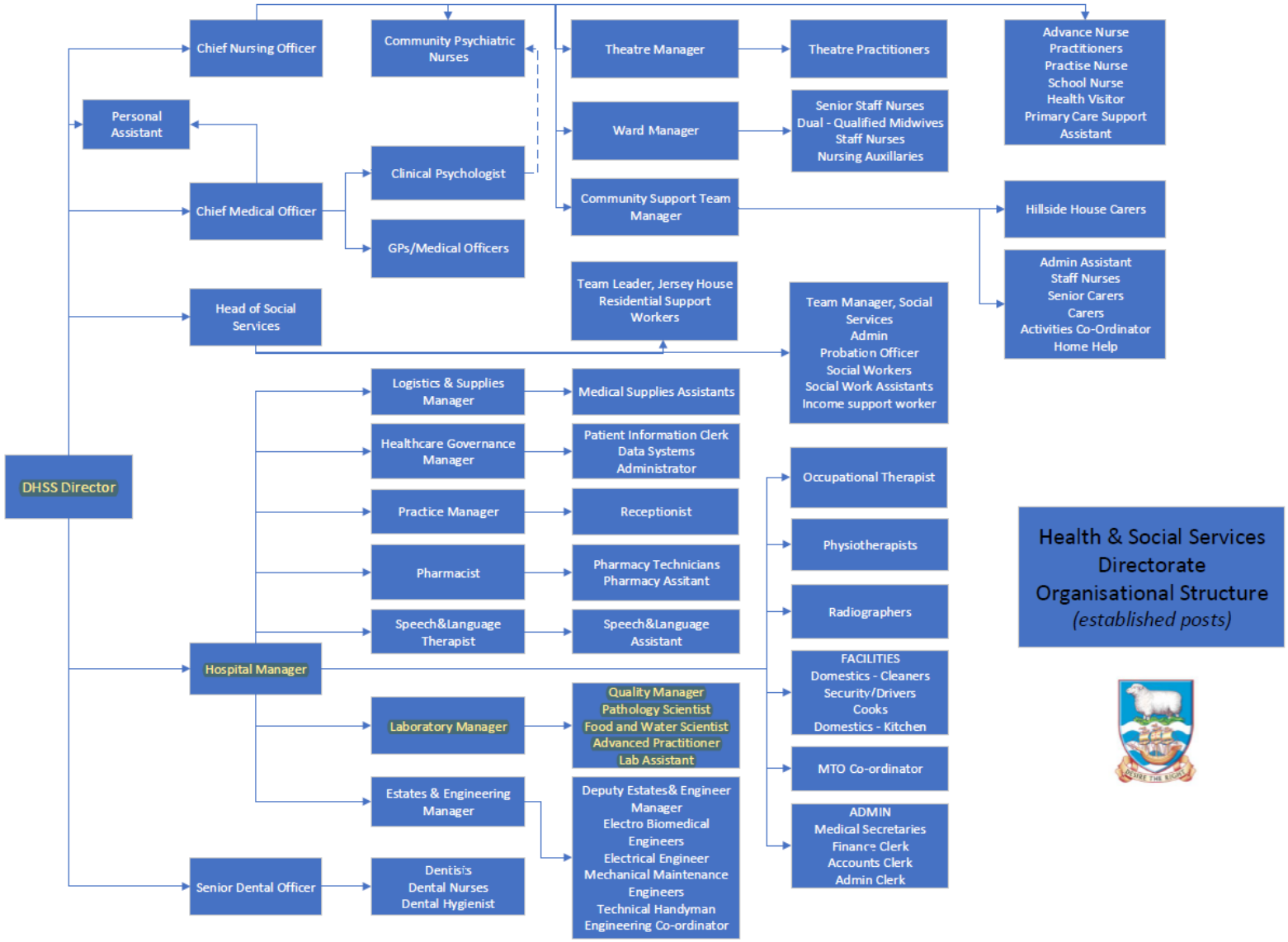

Figure 3: DHSS Structure

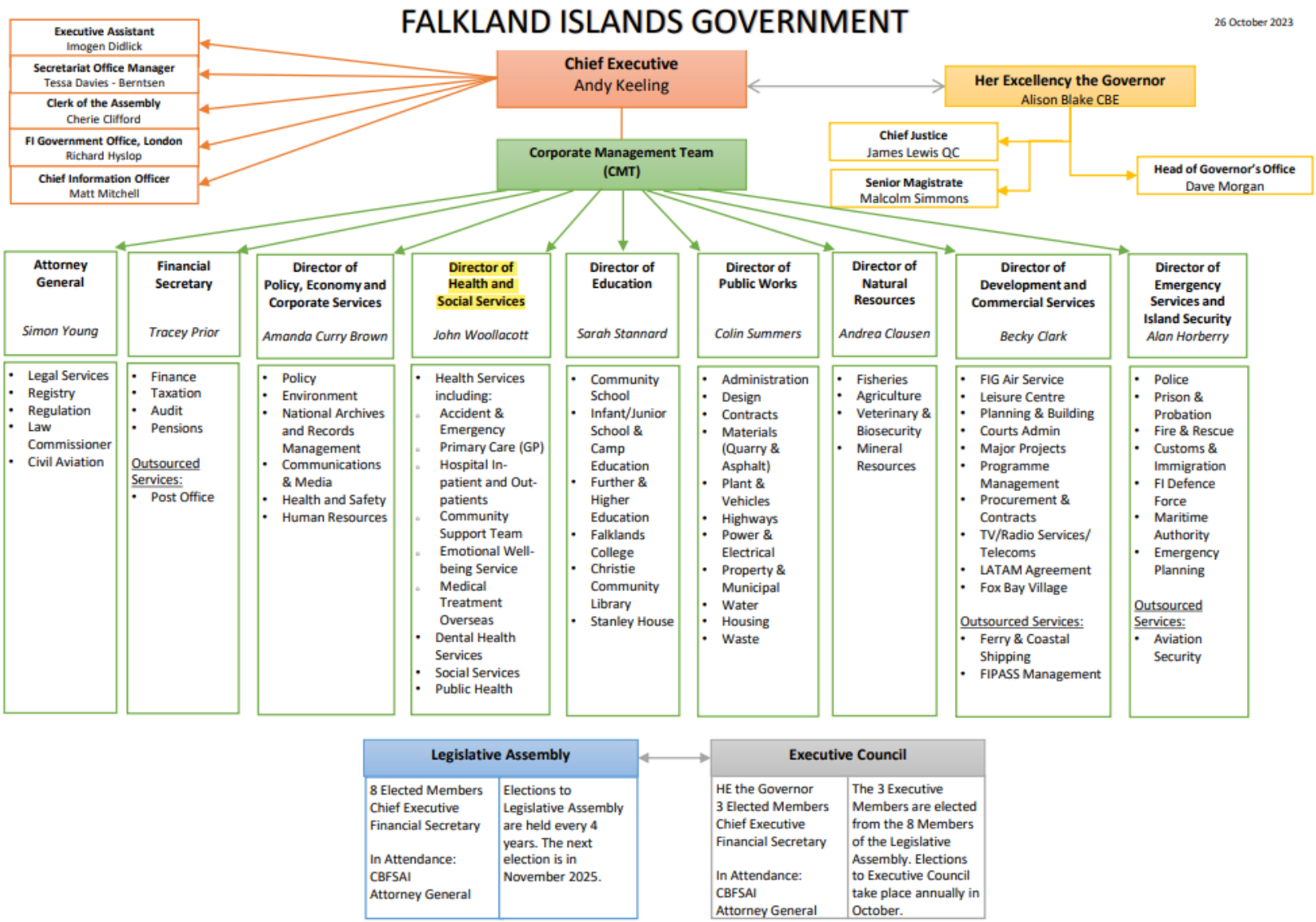

Figure 4: FIG Organogram

5.0 Impartiality and Confidentiality (ISO 17025 & 15189 Section 4)

5.1 The laboratory department (comprising of both FIG FWE laboratory and KEMH Clinical Pathology laboratories) is committed to the delivery of an impartial and confidential service.

5.2 Customers/service users entrust the laboratory department with sensitive information as part of the analytical services provided. They do so with the legitimate expectation that staff will respect individuals', government departments' and private businesses' right to privacy.

5.3 It is essential that the department provides a confidential service to all of our clients/users, and can provide the services of both laboratory sections without impinging or detrimentally affecting the service provision in either section through the use of shared staff and resources.

5.4 LAB-POL-1 (Impartiality and Confidentiality Policy) makes explicit the management, laboratory and personnel responsibilities and actions to safeguard impartiality and confidentiality.

5.5 Impartiality

5.5.1 The principles underlying impartiality are that the processes carried out in the two sections of the KEMH laboratory should be free from conflict of interests, free from bias, and free from prejudice.

5.5.2 The laboratory department provides two very different services under a single management structure; the two sections share resources including equipment and staff time.

5.5.3 The directorate recognises that the sharing of resources may impact impartiality, the biggest risk being that clinical workload may be given precedence over the FWE laboratory workload.

5.5.4 The laboratory makes every effort to mitigate this risk by taking the following actions;

- Employing a scientist that is dedicated solely to the FWE section
- Employing Biomedical scientists with varied specialist backgrounds to cover the clinical workload, including the provision of a 24/7 on-call services
- Using a staff rota to ensure support staff are present in the FWE section daily or when needed, without detriment to the clinical pathology section and vice versa.
- Using robust multi-disciplinary training programmes to ensure all work can be covered in the event of staff absences (annual leave, sick leave etc.)

5.5.5 The second risk is impartiality is due to the small size of the department establishment, creating opportunity of risks when reviewing the relationships of laboratory activities to personnel. This is most significantly when performing internal audits or reviewing documents (SOPs, CAPAs etc), where staff may find themselves auditing their own work.

5.5.6 The final risk is that of conflict of interest. Namely personal interest that may conflict with our responsibilities and decision making in relation to the laboratory activities. This may be an outside activity or it may present itself during routine activity. Examples of potential conflict of interest are as follows;

- Having a personal relationship with an individual that is part of a service user company e.g. fishing company having its product tested in this facility
- Receiving clinical samples from a relative or personal friend

5.5.7 The laboratory will mitigate these risks by asking staff to sign and submit a statement confirming ongoing impartiality awareness and declaration of impartiality as part of annual staff appraisal process (see PDP records).

5.5.8 Staff will mitigate these risks by performing the following actions;

- When performing laboratory activities such as audits, document reviews, CAPA investigations etc, staff will highlight and delegate tasks where possible, or seek secondary sign off where it is not. Staff should always document where they have undertaken a task that required them to review their own work.
- When receiving clinical specimens from relatives or friends, staff will delegate processing to an alternate member of staff. If this occurs outside of normal working hours the lone working on-call BMS must process the sample(s) regardless of conflict of interest issues, but should highlight the event to a colleague at the next available opportunity, who shall review processing and reporting of said sample(s). Review process will be documented on the LIMS.

5.5.9 Management will continually re-evaluate the laboratory need for resources to safe-guard impartiality at the management review meetings.

5.5.10 Management shall not allow commercial, financial or other pressures to compromise impartiality.

5.6 Confidentiality

5.6.1 The principles underlying confidentiality in the Health and Social Services Directorate are based on the Caldicott Principles adopted by the NHS in the UK.

5.2.2 The same principles are applied to FWE laboratory clients/users, the principles are:

- Justify the purpose.
- Do not use patient/client identifiable information unless it is absolutely necessary.
- Use the minimum necessary patient/client identifiable information.
- Access to a patient's/client's identifiable information should be on a strict need to know basis.
- Everyone should be aware of their responsibilities.

5.2.3 All user information must be kept private. This includes:

- Not gossiping.
- Not accessing records without a good reason.
- Taking care not to discuss information in a public place.
- Being aware of the dangers of breaching confidentiality inadvertently by discussing non-confidential aspects of a request.

5.2.4 All service user information must be kept physically and electronically secure. All electronic records must be kept in secure storage locations and confidential data storage minimised as far as practically possible. Staff should not leave computers logged in unless the screen is locked, and the removal of electronic media containing confidential information must not be taken from the department without the express approval of the laboratory manager.

5.2.4 Physical records must be stored in the appropriate files in a location accessible to authorised laboratory staff only. This includes offices/laboratories with a secure electronic access system. The doors to these locations must be kept closed when a member of staff is not present.

5.2.5 The reporting of results must be in line with established operating procedures for the reporting of results via telephone and electronic mail. No deviations are acceptable.

5.2.6 All enquiries about requests and results must establish the identity of the enquirer to ensure that only authorised customers for the FWE section and clinicians for the clinical pathology section are provided with the information.

5.2.7 Information may be disclosed between laboratory staff for the following reasons:

- Monitoring the quality of lab services e.g. via audit
- Co-ordinating testing with a referral laboratory.
- Effective management e.g. service planning, contracting, etc.
- Education and training.
- Statistical analysis.
- Continuation of service e.g. staff handovers

5.2.8 When the laboratory is required by law or authorised by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

5.2.9 Information about the service user obtained from sources other than the customer (e.g. complainant or competent authority) shall be confidential between the service user and the laboratory. The provider (source) of any such information shall be confidential to the laboratory and shall not be shared with the service user, unless agreed by the source.

5.2.10 For further information on confidentiality please refer to the FIG Department of Health and Social Services Code of Confidentiality (KEMH-Live Database GEN-POL-13)

6.0 Management System (ISO 17025 & 15189 Section 8)

The laboratory has established a management system that is capable of supporting and consistently achieving the management system requirements as defined in Section 8A of BS EN ISO 17025:2017. The details of key areas of this system are described here.

6.1 Management system documentation

6.1.1 All laboratory management system documentation policies, procedures, reference material, meeting minutes, training logs, validation reports and form templates are retained on the Q-Pulse system under the database 'Pathology-Live'.

6.1.2 All DHSS policies and procedures are maintained on the Q-Pulse system under the database 'KEMH-Live'.

6.1.3 All Overarching FIG policies are published on the FIG Intranet Document Library.

6.1.4 All three digital locations are accessible by all laboratory staff and by the Laboratory management group, allowing all personnel involved in laboratory activities to access the management system.

6.2 Control of management system documentation

6.2.1 Use of the Q-Pulse software allows excellent digital audit trail for all activities undertaken on the Q-Pulse document module including electronic document distribution and acknowledgement, documentation archive and documentation of change control.

6.2.2 LAB-POL-2 (Document Control policy) details the staff responsibilities within document control procedures and clearly defines how documents are uniquely identified and distributions is controlled.

6.2.3 LAB-SOP-18 (Document Control Procedures on Q-Pulse) describes how to perform the various steps of document creation, distributions, maintenance, archiving and deletion on the Q-Pulse Software.

6.3 Control of records

6.3.1 Laboratory processes create a large volume of records and as such must retain all pertinent data for suitable timeframes so they can be accessed if required.

6.3.2 LAB-POL-8 (Retention and Storage of Records and Specimens Policy) clearly defines staff responsibilities in physical and electronic record retention and clearly states location of record (including documentation) and duration of retention.

6.4 Actions to address risks and opportunities

6.4.1 The laboratory uses a variety of tools and mechanisms to capture and review risks, opportunities. Full details of these mechanisms can be found in LAB-POL-9 Management Review Policy.

6.4.2 Staff suggestions are acknowledged and escalated as detailed in LAB-SOP-23.

6.4.3 Staff engagement in quality meetings provides a forum for raising items to the attention of the management system.

6.4.4 The Laboratory risk register is maintained on the DHSS shared server as part of the directorate Risk Management documentation (Y:\Risk Management). Review of this is scheduled every two months.

6.4.5 Internal audit of the department is regularly undertaken, as per FWE-POL-17 and the audit schedule, findings and actions can be monitored through the Q-Pulse system.

6.4.6 Engagement with our customers through 'user group' sessions and performance questionnaires will be disseminated annually as per LAB-POL-9 (Management Review Policy) these processes may highlight risks and opportunities that will then be fed into the management system for evaluation.

6.4.7 Requests for tests/investigations not currently provided by KEMH laboratory are logged (see FWE-POL-16 section 5.3.8) and monitored as per LAB-SOP-22 (Quality Indicators SOP), and reviewed to inform the laboratory staff and management team of potential opportunities to expand the scope of our test repertoire.

6.5 Improvement

6.5.1 The KEMH laboratory uses many of the management system tools and procedures to identify opportunities for improvement, this include but are not limited to;

- Document review
- Departmental objectives
- Audit results
- Corrective actions
- Management review
- Staff suggestions
- User feedback
- Risk assessment
- Workload data analysis
- External quality assurance results

6.5.2 Engagement with our customers through 'user group' sessions, performance questionnaires and any complaints or compliments received and logged as per LAB-POL-9 (Management Review Policy). These processes seek to inform the management system of all positive and negative feedback for evaluation and opportunities for improvement.

6.6 Corrective actions

6.6.1 The When a nonconformity (NC) occurs the laboratory will record all instances and log all actions taken to correct or mitigate the nonconformity as per LAB-POL-10 (Non-conformance and CAPA policy).

6.6.2 All NCs logged on the Q-Pulse CAPA module to allow proper documentation of NC root cause analysis and provide the data to allow trend analysis of NCs; which may then impact on resourcing requirements, risk register or the management system as a whole.

6.7 Internal audits

6.7.1 The laboratory shall conduct regular internal audits as per a planned schedule (documented on the Q-Pulse Audit module) to assess conformity to out departmental policies and procedures and also conformity to any reference standards i.e. ISO 17025 or ISO 15189.

6.7.2 Audit activities and responsibilities are defined in LAB-POL-11.

6.8 Management reviews

6.8.1 Management review facilitates informed decision-making using data collated from various quality tools and activities (quality indicators, risk register, feedback, non-conformance records, audit findings etc) to identify opportunities for improvement and review and management of risks.

6.8.2 Management review of the KEMH Laboratory is a multifaceted process designed to engaged staff and users at all levels with information and dialogue appropriate to stakeholder roles and responsibilities.

6.8.3 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness.

6.8.2 The Laboratory Management Review Policy (LAB-POL-9) details the roles and responsibilities of the management team and laboratory staff, and clearly defines avenues and collation of input and output of management review tools and systems.

7.0 Resource Requirements (ISO 17025 & 15189 Section 6)

7.1 Personnel

7.1.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

7.1.2 The Laboratory Training Policy (LAB-POL-3) makes explicit the standards of conduct expected from laboratory staff in matters of training, provides mechanisms to enable targeted staff training, identifies key areas for staff training and ensures adequate training and competency records are maintained.

7.2 Facilities and environmental conditions

7.2.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

7.2.2 The KEMH laboratory has segregated its testing operations into three functional laboratories; Food, water & environmental microbiology laboratory, Clinical Microbiology laboratory and the Clinical blood sciences laboratory.

7.2.3 The Laboratory Environment Policy (LAP-POL-7) states the cleaning and environmental monitoring practices undertaken by the department to reduce risks of contamination.

7.3 Equipment

7.3.1 The laboratory has an array of equipment in house to perform the testing service provision. All equipment is supported by a standard operating procedure, which will detail all the aspects of equipment maintenance, quality control and calibration where relevant.

7.4 Metrological traceability

7.4.1 Metrological traceability is required for all equipment used for tests, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling.

7.4.2 The activities of the Food, Water and Environmental laboratory work is focussed on detection and enumeration of microorganisms using manual methods. Subsidiary measuring equipment such as pipettes and balances are either calibrated externally or internally to ensure metrological traceability where appropriate. Where calibration is performed in house, calibrated reference material is used in the calibration processes.

7.4.3 The activities of the pathology department where reliant on analyser-based methods, have analyser calibrations performed at regular intervals, determined by the analyser, analyte and internal performance. In these cases, calibrator material is used as recommended by the manufacturer.

7.5 Externally provided products and services

7.5.1 Suppliers of laboratory equipment, reagents and consumables are screened for information on quality management systems appropriate to the goods or services they provide.

7.5.2 Suppliers of calibration services e.g. for pipettes and reference weights must hold accreditation to ISO17025 and be able to supply calibration certificates.

7.5.3 Proof of technical capability and competence must be held for the provision of a service. Where possible this should be accredited and certified competence in the service being provided.

7.5.4 Full details of supplier requirements, assessment and management can be found in LAB-POL-13.

8.0 Process Requirements (ISO 17025 & 15189 Section 7)

8.1 Review of requests and contracts

8.1.1 The laboratory reviews the volume of each type of test request received through statistical workload analysis. This information is monitored at the Laboratory Quality Meetings, and reviewed annually at Laboratory Management review meetings, including identification of trends and anomalies.

8.1.2 Customer/Service user requests for tests that are not performed in house are logged and reviewed at monthly quality management meetings.

8.1.3 Potential new customers for Food, Water & environmental testing services are asked to complete a client information form detailing the type and frequency of testing they are seeking. These

are reviewed by the laboratory manager, the departmental ability to meet the demands of the prospective workload are assessed before a new customer is accepted.

8.2 Selection, verification and validation of methods

8.2.1 The laboratory endeavours to ensure that methods are sufficiently validated before use in client testing requests. Prior to implementing a method, the laboratory will complete a short study to determine precision and accuracy within the intended method. Where appropriate the limit of detection will also be established.

8.2.2 Within the FWE laboratory only ISO reference methods will be used as the laboratory is not equipped to carry out full validation studies for in-house methods in relation to BS EN ISO 16140-2:2016.

8.2.3 Within the Clinical Pathology laboratory method selection is more complex. The laboratory selects examination procedures which have been validated for their intended use. The specified performance specifications for each examination procedure relate to the intended use of that examination. Preferred procedures are those specified in the instructions for use of in vitro medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in the international consensus standards or guidelines, or national or regional regulations.

8.3 Sampling

8.3.1 The KEMH Laboratory department does not perform sampling.

8.3.2 Within the scope of food and water testing, design of sampling strategies and collection of samples shall be the responsibility of the client. The FWE Laboratory will hold no responsibility for creating, documenting or monitoring sampling. The FWE laboratory will provide customers with appropriate sample collection devices/containers.

8.3.3 The Clinical pathology laboratory will provide information for the proper collection and handling of primary samples, completing sample request forms (electronic and/or paper) and the departmental sample acceptance policy. The correct collection samples and associated request forms, shall be the responsibility of the clinical staff requesting the service.

8.4 Handling of test items

8.4.1 All test items will be assigned a unique laboratory identification number. This number should be associated with the test item from request receipt to report distribution.

8.4.2 Test items intended for investigation by the FWE laboratory should be handled and transported as per the provided instructions in customer specific service level agreements. The laboratory shall provide sample collection devices and transport containers (cool boxes) upon request by customers.

8.4.3 The Clinical Pathology laboratory instructions for sample collection include comments on any specific sample transport instruction.

8.4.4 Upon receipt all samples are checked against specific criteria which determines if a sample is fit for testing by assessing the sample collection time and appropriateness of container, preservatives, and temperature considerations if appropriate.

8.4.5 Where there are problems with sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or

irreplaceable and the laboratory chooses to process the sample, the final report will indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.

8.5 Technical records

8.5.1 Technical records are request forms, worksheets, maintenance logs, analyser results and data entered to and calculated by software.

8.5.2 LAB-POL-8 (Retention and Storage of Records and Specimens Policy) clearly defines staff responsibilities in physical and electronic record retention and clearly states location of records and duration of retention.

8.5.3 The KEMH laboratory ensures that technical records for each laboratory activity contain the results and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and enable the repetition of the laboratory activity under conditions as close as possible to the original. Technical records shall include the date and the identity of the personnel responsible for each laboratory activity and for checking data and results.

8.5.4 The laboratory ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data is retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

8.6 Evaluation of measurement of uncertainty

8.6.1 The KEMH laboratory will identify the contributions to measurement uncertainty.

8.6.2 the KEMH laboratory shall evaluate measurement uncertainty in a way suitable to the principles of the method.

8.6.3 Upon request the laboratory shall make its estimates of measurement uncertainty available to clients and/or users.

8.7 Ensuring the validity of results

8.7.1 The KEMH shall monitor the validity of results. Where practical this will encompass detecting trends or deviation from trends using statistical techniques. This will include a combination of the following:

- the use of quality control materials, including blanks/sterile material
- functionality checks of measuring and testing equipment
- control charts or logs
- intermediate checks on measuring equipment
- replicate tests
- retesting of retained items
- review of reported results
- interlaboratory comparisons (through participation in an EQA scheme)
- testing of blind samples

8.7.2 the KEMH laboratory shall continuously monitor its performance against results of other laboratories where available and appropriate, by participating in proficiency testing schemes that cover the range of testing undertaken in the department.

8.7.3 Data from monitoring activities shall be analysed, used to control and improve the laboratory's service provision.

8.7.4 If results from monitoring activities are outside of pre-defined acceptance limits action shall be taken to prevent incorrect results from being reported.

8.8 Reporting of results

8.8.1 Testing results shall be provided accurately, clearly, unambiguously and objectively, usually in standard test report format, and shall include all the information supplied by the customer/service user to enable identification of the source of the sample.

8.8.2 All issued reports shall be retained as technical records.

8.8.3 In relation to food and water sample test reports The Falkland Islands Government (FIG) has designated the Veterinary Service (VS) at the Department of Agriculture (DOA) as the "Competent Authority (CA)" for the purposes of inspecting and certifying meat and fish product, destined for export, as being fit for human consumption. The CA makes use of the services of the FWE laboratory to:

a) Determine that meat and fish product has been processed in a hygienic manner as required by the European Union specifically Regulations 178/2002, 852/2004, 853/2004 and 2017/625.

b) Determine if potable water samples collected during inspections are fit for consumption.

The KEMH laboratory will not list any opinions or interpretations as to the significance of these results nor as to the fitness of a sample for its intended purpose.

8.8.4 Clinical Pathology results are reported with biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable.

8.8.5 In all cases when an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

8.8.6 Amendments to a report after issue shall be made in the form of a further report document (paper or electronic) which includes the statement "Amended report".

8.9 Complaints

8.9.1 The KEMH laboratory is committed to providing the best possible service to users/clients and welcomes both negative and positive feedback to continually improve the service offered. This may come in the form of a complaint or a compliment. Complaints are indications that clients have bad/unsatisfactory experience with a certain aspect of the services delivered by the laboratory. This is a good indication of where an improvement may be made. It is therefore necessary to handle all complaints in the same systematic manner as any non-conformance. However, in dealing with a complaint the complainant should be informed of the outcome of the investigation.

8.9.2 Positive comments or compliments about our services are also very welcome, and provide a great morale booster for staff. They also ensure that we do not make changes that would impact on the positive aspects of our service.

8.9.3 The Department of Health and Social Services has an overarching complaints policy (GEN-POL-6) which is held electronically on the KEMH-Live Q-Pulse database and is freely available to download by service users from https://www.falklands.gov.fk/health/downloads

8.9.4 Complaints shall be handled in the KEMH Laboratory department according to the procedures defined in LAB-SOP-24 (Complaints Procedure).

8.10 Nonconforming work

8.10.1 The KEMH laboratory department is committed to maintaining a policy of monitoring performance, ensuring reliable test results and to provide a standard procedure for containing and correcting results that do not conform to the agreed standards of practice.

8.10.2 All nonconforming aspects of laboratory work, equipment, documentation or systems must be recorded on the Q-Pulse CAPA module, thus creating a non-conformance (NC) record and investigation template.

8.10.3 All NC records on the CAPA module should be assigned a severity level, these are categorised as follows:

High: Released/reported/validated results have been affected or causes a service failure

Med: Reported results not affected or could result in service failure

Low: NC found before any testing has taken place e.g. IQC and maintenance checks or no impact on service provision

8.10.4 Laboratory staff must take actions to control and correct all nonconformances as they occur, recording these actions in the NC investigation template under 'immediate action'.

8.10.5 Impact assessment must be logged to detail the extent and impact of the nonconformance on laboratory output i.e. tests results.

8.10.6 Root cause analysis must be undertaken for all NC investigations, including potential/near miss records.

8.10.7 Corrective actions appropriate to the nonconformance must be implemented to counteract the 'root cause'

where reasonably possible.

8.10.8 For 'near miss', or 'potential' nonconformance incidents the NC report on the CAPA module should log any preventative actions undertaken to resolve the identified short comings.

8.10.9 Upon completion of the investigation stages of the CAPA the Quality manager will review the actions that have been undertaken, and when satisfied will complete the NC record categorisations at the top of the record, and assign follow up actions (to ensure that corrective actions are fit for purpose) where necessary.

8.10.10 Upon completion of the follow up action(s) the Quality Manager will close the NC record.

8.10.11 NCs will be reviewed at the monthly Quality Management meeting and at Management Review meetings.

8.10.12 If a NC has had any effect on a client/servicer user's work, including validated/reported results the client will be contacted and informed by the Laboratory Manager or Quality Manager. This contact will include details of the NC, details of the results it may have affected and the severity.

8.10.13 If an NC results in the laboratory being unable to complete some/all of the requested investigations the lab will notify affected service users in advance of sample submission/test requesting, and provide an update of NC resolution within 1 working day of resolution implementation. Likely sources of NC which would prevent the laboratory from completing investigations are logistics failure (on site supply exhausted before re-supply received), or failure of department autoclaves (creating an inability to manufacture culture media on site). Both these issues are highlighted as operational risks on the department risk register, and are difficult to mitigate against fully due to the nature of risk factors.

8.11 Control of data and information management

8.11.1 The KEMH laboratory information management systems are used for the collection, processing, recording, reporting, storage and retrieval of data.

8.11.2 The information management system is protected from unauthorised access by physical departmental security provisions and data security provisions inherent in the server structure. Only authorised personnel have access to the systems and access is further regulated by secure password access and specific user authorities assigned according to operator job roles. Data held electronically on the server is backed up every 24 hours to preserve data and system integrity in the event of failure.

8.11.3 Full details of the FIG IT system are provided in the appendix of LAB-POL-7 (Laboratory Environmental Policy).

8.11.4 It should be noted that there is no provision for air-gapping backups within Falkland Islands Government, or the Falklands as a whole. This is a known accepted national risk.

9.0 Record of changes within document revision

Document Version	Date of revision	Change/Addition Description
2	14/12/2023	4.0 Structural Requirements: Updated all structural diagrams including Laboratory establishment, DHSS establishment and FIG Organogram. DHSS and laboratory pathways highlighted for ease of review. Added Laboratory Department KSE technical escalation structure
2	14/12/2023	5.0 Impartiality & Confidentiality: Updated impartiality statements to align with revised LAB-POL-1 V3. Expansion of impartiality risks and mitigations.
2	14/12/2023	6.0 Management System sections 6.4, 6.5 and 6.8 – Revised to reference LAB-POL-9 Management Review Policy, and correct Risk Register location.
2	14/12/2023	7.0 Resource Requirements section 7.5 Externally provided products and services – Revised to reference new overarching LAB-POL-13 Supplier Approval & Management Policy
2	14/12/2023	Section 8.0 Process requirements, section 8.9 Complaints – additional reference to LAB-SOP-24 Complaints Procedure.
2	14/12/2023	Section 8.0 Process requirements, section 8.10 Nonconforming work – Expanded to identify specific risks to department service provision in the form of media preparation and logistic disruption, includes actions to be taken to inform clients.
2	14/12/2023	Section 8.0 Process requirements, section 8.11 Control of data and information management – expanded to identify where information on FIG IT system structure can be found.
3	27/01/2025	1.3 To add information regarding where to find UKAS accredited scope of testing